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2015-05-15

**Systems and software engineering — System life cycle processes**

*Ingénierie des systèmes et du logiciel — Processus du cycle de vie du système*

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**Foreword**

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work. In the field of information technology, ISO and IEC have established a joint technical committee, ISO/IEC JTC 1.

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The main task of ISO/IEC JTC 1 is to prepare International Standards. Draft International Standards adopted by the joint technical committee are circulated to national bodies for voting. Publication as an International Standard requires approval by at least 75 % of the national bodies casting a vote.

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ISO/IEC/IEEE 15288 was prepared by Joint Technical Committee ISO/IEC JTC 1, *Information technology*, Subcommittee SC 7, S*oftware and systems engineering*, in cooperation with the IEEE Computer Society Systems and Software Engineering Standards Committee, under the Partner Standards Development Organization cooperation agreement between ISO and IEEE.

This first edition of ISO/IEC/IEEE 15288 cancels and replaces the ISO/IEC 15288:2008 (second edition), which has been technically revised.

Changes in this revision of ISO/IEC/IEEE 15288 were developed in conjunction with a corresponding revision of ISO/IEC/IEEE 12207, *Systems and software engineering – Software life cycle processes*. The purpose of these revisions is to accomplish the harmonization of the structures and contents of the two International Standards, while supporting the requirements of the assessment community.

This International Standard was developed with the following goals:

provide a common terminology between the revision of the ISO/IEC/IEEE 15288 and ISO/IEC/IEEE 12207,

where applicable, provide common process names and process structure between the revision of the ISO/IEC/IEEE 15288 and ISO/IEC/IEEE 12207,

enable the user community to evolve towards fully harmonized standards, while maximizing backward compatibility.

This revision is intended to achieve a fully harmonized view of the system and software life cycle processes.

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**Introduction**

The complexity of man-made systems has increased to an unprecedented level. This has led to new opportunities, but also to increased challenges for the organizations that create and utilize systems. These challenges exist throughout the life cycle of a system and at all levels of architectural detail. This International Standard provides a common process framework for describing the life cycle of systems created by humans, adopting a Systems Engineering approach. Systems Engineering is an interdisciplinary approach and means to enable the realization of successful systems. It focuses on defining stakeholder needs and required functionality early in the development cycle, documenting requirements, then proceeding with design synthesis and system validation while considering the complete problem. It integrates all the disciplines and specialty groups into a team effort forming a structured development process that proceeds from concept to production to operation. It considers both the business and the technical needs of all stakeholders with the goal of providing a quality product that meets the needs of users and other applicable stakeholders. This life cycle spans the conception of ideas through to the retirement of a system. It provides the processes for acquiring and supplying systems. It helps to improve communication and cooperation among the parties that create, utilize and manage modern systems in order that they can work in an integrated, coherent fashion. In addition, this framework provides for the assessment and improvement of the life cycle processes.

The processes in this International Standard form a comprehensive set from which an organization can construct system life cycle models appropriate to its products and services. An organization, depending on its purpose, can select and apply an appropriate subset to fulfill that purpose.

This International Standard can be used in one or more of the following modes:

By an organization — to help establish an environment of desired processes. These processes can be supported by an infrastructure of methods, procedures, techniques, tools and trained personnel. The organization may then employ this environment to perform and manage its projects and progress systems through their life cycle stages. In this mode this International Standard is used to assess conformance of a declared, established environment to its provisions.

By a project — to help select, structure and employ the elements of an established environment to provide products and services. In this mode this International Standard is used in the assessment of conformance of the project to the declared and established environment.

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By an acquirer and a supplier — to help develop an agreement concerning processes and activities. Via the agreement, the processes and activities in this International Standard are selected, negotiated, agreed to and performed. In this mode this International Standard is used for guidance in developing the agreement.

By process assessors — to serve as a process reference model for use in the performance of process assessments that may be used to support organizational process improvement.

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**IEEE Introduction**

This introduction is not part of IEEE Std 15288™-2015, Systems and Software Engineering — Systems Life Cycle Processes.

This standard replaces ISO/IEC/IEEE Std 15288™-2008, Systems and software engineering—System life cycle processes. That standard replaced IEEE Std 15288™-2004, Adoption of ISO/IEC 15288:2002, Systems and software engineering—System life cycle processes. The original ISO/IEC 15288 was published in November 2002 and was the first international standard to provide a comprehensive set of life cycle processes for systems.

This new revision of ISO/IEC/IEEE 15288 is the product of a coordinated effort by IEEE and ISO/IEC JTC 1/SC 7. The base document for the revision is the ISO/IEC/IEEE standard. Development of this revision was carefully coordinated with the parallel revision of ISO/IEC/IEEE 12207:2015 to align structure, terms, and corresponding organizational and project processes.

This revised standard is a step in the SC7 harmonization strategy to achieve a fully integrated suite of system and software life cycle processes and guidance for their application. It is also an important step in the shared strategy of ISO/IEC JTC 1/SC 7 and the IEEE to harmonize their respective collections of standards.

**Notice to users**

**Errata**

Errata, if any, for this and all other standards can be accessed at the following URL: http:// standards.ieee.org/reading/ieee/updates/errata/index.html. Users are encouraged to check this URL for errata periodically.

**Interpretations**

Current interpretations can be accessed at the following URL: http://standards.ieee.org/reading/ieee/interp/ index.html.

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**Systems and software engineering — System life cycle processes**

**1** **Overview**

**1.1 Scope**

This International Standard establishes a common framework of process descriptions for describing the life cycle of systems created by humans. It defines a set of processes and associated terminology from an engineering viewpoint. These processes can be applied at any level in the hierarchy of a system’s structure. Selected sets of these processes can be applied throughout the life cycle for managing and performing the stages of a system's life cycle. This is accomplished through the involvement of all stakeholders, with the ultimate goal of achieving customer satisfaction.

This International Standard also provides processes that support the definition, control and improvement of the system life cycle processes used within an organization or a project. Organizations and projects can use these processes when acquiring and supplying systems.

This International Standard concerns those systems that are man-made and may be configured with one or more of the following system elements: hardware, software, data, humans, processes (e.g., processes for providing service to users), procedures (e.g., operator instructions), facilities, materials and naturally occurring entities.

When a system element is software, the software life cycle processes in ISO/IEC/IEEE 12207:2015 may be used to implement that system element. The two standards are harmonized for concurrent use on a single project or in a single organization.

**1.2 Purpose**

The purpose of this International Standard is to provide a defined set of processes to facilitate communication among acquirers, suppliers and other stakeholders in the life cycle of a system.

This International Standard applies to organizations in their roles as both acquirers and suppliers. It can be used by a single organization in a self-imposed mode or in a multi-party situation. Parties can be from the same organization or from different organizations and the situation can range from an informal agreement to a formal contract.

The processes in this International Standard can be used as a basis for establishing business environments, e.g., methods, procedures, techniques, tools and trained personnel. Annex A provides normative direction regarding the tailoring of these system life cycle processes.

**1.3 Field of application**

This International Standard applies to the full life cycle of systems, including conception, development, production, utilization, support and retirement of systems, and to the acquisition and supply of systems, whether performed internally or externally to an organization. The life cycle processes of this International Standard can be applied concurrently, iteratively and recursively to a system and incrementally to its elements.

There is a wide variety of systems in terms of their purpose, domain of application, complexity, size, novelty, adaptability, quantities, locations, life spans and evolution. This International Standard describes the processes that comprise the life cycle of man-made systems. It therefore applies to one-of-a-kind systems, mass-produced systems and customized, adaptable systems. It also applies to a complete stand-alone system and to systems that are embedded and integrated into larger more complex and complete systems.

This International Standard provides a process reference model characterized in terms of the process purpose and the process outcomes that result from the successful execution of the activity tasks. Annex B lists examples of artifacts and information items that may be associated with various processes. This International Standard can therefore be used as a reference model to support process assessment as specified in ISO/IEC

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15504-2:2003. Annex C provides information regarding the use of the system life cycle processes as a process reference model. Annex D describes the process constructs for use in the process reference model.

**1.4 Limitations**

This International Standard does not prescribe a specific system life cycle model, development methodology, method, model or technique. The users of this International Standard are responsible for selecting a life cycle model for the project and mapping the processes, activities, and tasks in this International Standard into that model. The parties are also responsible for selecting and applying appropriate methodologies, methods, models and techniques suitable for the project.

Although this International Standard does not establish a management system, it is intended to be compatible with the quality management system provided by ISO 9001, the service management system provided by ISO/IEC 20000-1:2011 (IEEE Std 20000-1-2013), and the information security management system provided by ISO/IEC 27000.

This International Standard does not detail information items in terms of name, format, explicit content and recording media. ISO/IEC/IEEE 15289 addresses the content for life cycle process information items (documentation).

**2** **Conformance**

**2.1 Intended usage**

The requirements in this International Standard are contained in Clause 6 and Annex A. This International Standard provides requirements for a number of processes suitable for usage during the life cycle of a system or product. It is recognized that particular projects or organizations may not need to use all of the processes provided by this International Standard. Therefore, implementation of this International Standard typically involves selecting and declaring a set of processes suitable to the organization or project. There are two ways that an implementation can be claimed to conform to the provisions of this International Standard – full conformance and tailored conformance.

There are two criteria for claiming full conformance. Achieving either criterion suffices for conformance, although the chosen criterion (or criteria) is to be stated in the claim. Claiming “full conformance to tasks” asserts that all of the requirements of the activities and tasks of the declared set of processes are achieved. Alternatively, claiming “full conformance to outcomes” asserts that all of the required outcomes of the declared set of processes are achieved. Full conformance to outcomes permits greater freedom in the implementation of conforming processes and may be useful for implementing processes to be used in the context of an innovative life cycle model.

NOTE 1 Options for conformance are provided for needed flexibility in the application of this International Standard. Each process has a set of objectives (phrased as “outcomes”) and a set of activities and tasks that represent one way to achieve the objectives.

NOTE 2 Users who implement the activities and tasks of the declared set of processes can assert full conformance to tasks of the selected processes. Some users, however, might have innovative process variants that achieve the objectives (i.e., the outcomes) of the declared set of processes without implementing all of the activities and tasks. These users can assert full conformance to the outcomes of the declared set of processes. The two criteria—conformance to task and conformance to outcome—are necessarily not equivalent since specific performance of activities and tasks may require, in some cases, a higher level of capability than just the achievement of outcomes.

NOTE 3 When this International Standard is used to help develop an agreement between an acquirer and a supplier, clauses of this International Standard can be selected for incorporation in the agreement with or without modification. In this case, it is more appropriate for the acquirer and supplier to claim compliance with the agreement than conformance with this International Standard.

NOTE 4 An organization (for example, national, industrial association, company) imposing this International Standard as a condition of trade can specify and make public the minimum set of required processes, outcomes, activities, and tasks, which constitute suppliers' compliance with the conditions of trade.

NOTE 5 Requirements of this International Standard are marked by the use of the verb "shall". Recommendations are marked by the use of the verb "should". Permissions are marked by the use of the verb "may". However, despite the verb that is used, the requirements for conformance are selected as described previously.

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**2.2 Full conformance**

**2.2.1** **Full conformance to outcomes**

A claim of full conformance declares the set of processes for which conformance is claimed. Full conformance to outcomes is achieved by demonstrating that all of the outcomes of the declared set of processes have been achieved. In this situation, the provisions for activities and tasks of the declared set of processes are guidance rather than requirements, regardless of the verb form that is used in the provision.

NOTE One intended use of this International Standard is to facilitate process assessment and improvement. For this purpose, the objectives of each process are written in the form of 'outcomes' compatible with the provisions of ISO/IEC 15504-2 and ISO/IEC 33002. Those standards provide for the assessment of the processes of this International Standard, providing a basis for improvement. Users intending process assessment and improvement may use the process outcomes written in this International Standard as the "process reference model" required by ISO/IEC 15504-2 and ISO/IEC 33002.

**2.2.2** **Full conformance to tasks**

A claim of full conformance declares the set of processes for which conformance is claimed. Full conformance to tasks is achieved by demonstrating that all of the requirements of the activities and tasks of the declared set of processes have been achieved. In this situation, the provisions for the outcomes of the declared set of processes are guidance rather than requirements, regardless of the verb form that is used in the provision.

NOTE A claim of full conformance to tasks may be appropriate in contractual situations where an acquirer or a regulator requires detailed understanding of the suppliers‘ processes.

**2.3 Tailored conformance**

When this International Standard is used as a basis for establishing a set of processes that do not qualify for full conformance, the clauses of this International Standard are selected or modified in accordance with the tailoring process prescribed in Annex A. The tailored text, for which tailored conformance is claimed, is declared. Tailored conformance is achieved by demonstrating that the outcomes, activities, and tasks, as tailored, have been achieved.

**3** **Normative references**

None.

**4** **Terms, definitions, and abbreviated terms**

**4.1 Terms and definitions**

For the purposes of this document, the following terms and definitions apply.

NOTE Definitions for other terms typically can be found in ISO/IEC/IEEE 24765, available at <www.computer.org/sevocab>.

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**4.1.1**

**acquirer**

stakeholder that acquires or procures a product or service from a supplier

Note 1 to entry: Other terms commonly used for an acquirer are buyer, customer, owner, purchaser or internal/organizational sponsor.

**4.1.2**

**acquisition**

process of obtaining a system, product or service

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**4.1.3**

**activity**

set of cohesive tasks of a process

**4.1.4**

**agreement**

mutual acknowledgement of terms and conditions under which a working relationship is conducted

EXAMPLE Contract, memorandum of agreement.

**4.1.5**

**architecture**

<system> fundamental concepts or properties of a system in its environment embodied in its elements, relationships, and in the principles of its design and evolution

[SOURCE: ISO/IEC/IEEE 42010:2011]

**4.1.6**

**architecture framework**

|  |  |
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| conventions, principles and practices for the description of architectures established within a specific domain | |
| -- |  |
| -`-`,,`,,,`,``,,,`,`,``,``,,,,,,` |  |
| of application and/or community of stakeholders | |
| EXAMPLE 1 | Generalized Enterprise Reference Architecture and Methodologies (GERAM) [ISO 15704] is an |
| architecture framework. | |
| EXAMPLE 2 | Reference Model of Open Distributed Processing (RM-ODP) [ISO/IEC 10746] is an architecture |
| framework.`,,`,,`,`,,` |  |
| --- |  |

[SOURCE: ISO/IEC/IEEE 42010:2011]

**4.1.7**

**architecture view**

work product expressing the architecture of a system from the perspective of specific system concerns

[SOURCE: ISO/IEC/IEEE 42010:2011]

**4.1.8**

**architecture viewpoint**

work product establishing the conventions for the construction, interpretation and use of architecture views to frame specific system concerns

[SOURCE: ISO/IEC/IEEE 42010:2011]

**4.1.9**

**audit**

independent examination of a work product or set of work products to assess compliance with specifications, standards, contractual agreements, or other criteria

[SOURCE: ISO 24765:2010]

**4.1.10**

**baseline**

formally approved version of a configuration item, regardless of media, formally designated and fixed at a specific time during the configuration item's life cycle

[SOURCE: IEEE Std 828-2012]

**4.1.11**

**concept of operations**

verbal and/or graphic statement, in broad outline, of an organization’s assumptions or intent in regard to an operation or series of operations

**4**

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Note 1 to entry: The concept of operations frequently is embodied in long-range strategic plans and annual operational

plans. In the latter case, the concept of operations in the plan covers a series of connected operations to be carried out simultaneously or in succession. The concept is designed to give an overall picture of the organization operations. See also operational concept.

Note 2 to entry: It provides the basis for bounding the operating space, system capabilities, interfaces and operating

environment.

[SOURCE: ANSI/AIAA G-043A-2012e]

**4.1.12**

**concern**

<system> interest in a system relevant to one or more of its stakeholders

Note 1 to entry: A concern pertains to any influence on a system in its environment, including developmental, technological, business, operational, organizational, political, economic, legal, regulatory, ecological and social influences.

[SOURCE: ISO/IEC/IEEE 42010:2011]

**4.1.13**

**configuration item**

item or aggregation of hardware, software, or both, that is designated for configuration management and treated as a single entity in the configuration management process

[SOURCE: ISO/IEC/IEEE 24765:2010, modified to include “item”]

**4.1.14**

**customer**

organization or person that receives a product or service

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EXAMPLE Consumer, client, user, acquirer, buyer, or purchaser.

Note 1 to entry: A customer can be internal or external to the organization.

[SOURCE: ISO 9000:2005, modified – added ‘service’]

**4.1.15**

**design,** verb

<process> to define the architecture, system elements, interfaces, and other characteristics of a system or system element

[SOURCE: ISO/IEC/IEEE 24765:2010, modified – changed 'components' to 'system elements]

**4.1.16**

**design,** noun

result of the process in 4.1.15

Note 1 to entry: Information, including specification of system elements and their relationships, that is sufficiently

complete to support a compliant implementation of the architecture.

Note 2 to entry: Design provides the detailed implementation-level physical structure, behavior, temporal relationships,

and other attributes of system elements.

[SOURCE: ISO/IEC/IEEE 24765:2010]

**4.1.17**

**design characteristic**

design attributes or distinguishing features that pertain to a measurable description of a product or service [SOURCE: ISO/IEC/IEEE 24765:2010]

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**4.1.18**

**enabling system**

system that supports a system-of-interest during its life cycle stages but does not necessarily contribute directly to its function during operation

EXAMPLE When a system-of-interest enters the production stage, a production-enabling system is required.

Note 1 to entry: Each enabling system has a life cycle of its own. This International Standard is applicable to each

enabling system when, in its own right, it is treated as a system-of-interest.

**4.1.19**

**environment**

<system> context determining the setting and circumstances of all influences upon a system [ISO/IEC/IEEE 42010:2011]

**4.1.20**

**facility**

physical means or equipment for facilitating the performance of an action, e.g., buildings, instruments, tools

**4.1.21**

**incident**

anomalous or unexpected event, set of events, condition, or situation at any time during the life cycle of a project, product, service, or system

**4.1.22**

**information item**

separately-- identifiable body of information that is produced, stored, and delivered for human use [SOURCE:`,,`,,,`,``,,,`,`,``,``,,,,,,` ISO/IEC/IEEE 15289:2011]

**4.1.23**

**life cycle** -

evolution`-`,,`,,`,`,,` of a system, product, service, project or other human-made entity from conception through retirement

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**4.1.24**

**life cycle model**

framework of processes and activities concerned with the life cycle that may be organized into stages, which also acts as a common reference for communication and understanding

**4.1.25**

**operational concept**

verbal and graphic statement of an organization’s assumptions or intent in regard to an operation or series of operations of a system or a related set of systems

Note 1 to entry: The operational concept is designed to give an overall picture of the operations using one or more specific systems, or set of related systems, in the organization’s operational environment from the users’ and operators’ perspective. See also concept of operations.

[SOURCE: ANSI/AIAA G-043A-2012e]

**4.1.26**

**operator**

individual or organization that performs the operations of a system

Note 1 to entry: The role of operator and the role of user can be vested, simultaneously or sequentially, in the same

individual or organization.

Note 2 to entry: An individual operator combined with knowledge, skills and procedures can be considered as an

element of the system.

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Note 3 to entry: An operator may perform operations on a system that is operated, or of a system that is operated,

depending on whether or not operating instructions are placed within the system boundary.

**4.1.27**

**organization**

group of people and facilities with an arrangement of responsibilities, authorities and relationships

EXAMPLE Company,

corporation,

firm,

enterprise,

institution,

charity,

sole

trader,

association,

or

parts

or

combination thereof.

Note 1 to entry: An identified part of an organization (even as small as a single individual) or an identified group of

organizations can be regarded as an organization if it has responsibilities, authorities and relationships. A body of persons organized for some specific purpose, such as a club, union, corporation, or society, is an organization.

[SOURCE: ISO 9000:2005, modified – Note 1 to entry has been added]

**4.1.28**

**party**

organization entering into an agreement

Note 1 to entry: In this International Standard, the agreeing parties are called the acquirer and the supplier.

**4.1.29**

**problem**

|  |  |
| --- | --- |
| difficulty, uncertainty, or otherwise realized and undesirable event, set of events, condition, or situation that | |
|  | --- |
| requires investigation and corrective action | -`-`,,`,,`,`,,` |
|  |
| **4.1.30** | --`,,`,,,`,``,,,`,`,``,``,,,,,,` |
| [SOURCE: ISO 9000:2005] |
| **process** |  |

set of interrelated or interacting activities that transforms inputs into outputs

**4.1.31**

**process purpose**

high level objective of performing the process and the likely outcomes of effective implementation of the process

Note 1 to entry: The purpose of implementing the process is to provide benefits to the stakeholders.

**4.1.32**

**product**

result of a process

Note 1 to entry: There are four agreed generic product categories: hardware (e.g., engine mechanical part); software (e.g., computer program); services (e.g., transport); and processed materials (e.g., lubricant). Hardware and processed materials are generally tangible products, while software or services are generally intangible.

[SOURCE: ISO 9000:2005]

**4.1.33**

**project**

endeavour with defined start and finish criteria undertaken to create a product or service in accordance with specified resources and requirements

Note 1 to entry: A project is sometimes viewed as a unique process comprising co-coordinated and controlled activities and composed of activities from the Project Processes and Technical Processes defined in this International Standard.

**4.1.34**

**quality assurance**

part of quality management focused on providing confidence that quality requirements will be fulfilled [SOURCE: ISO 9000:2005]

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**4.1.35**

**quality characteristic**

inherent characteristic of a product, process, or system related to a requirement

Note 1 to entry: Critical quality characteristics commonly include those related to health, safety, security, assurance, reliability, availability and supportability.

[SOURCE: ISO 9000:2005, modified – Note 1 to entry added]

**4.1.36**

**quality management**

coordinated activities to direct and control an organization with regard to quality [SOURCE: ISO 9000:2005]

**4.1.37**

**requirement**

statement that translates or expresses a need and its associated constraints and conditions [SOURCE: ISO/IEC/IEEE 29148:2011]

**4.1.38**

**resource**

asset that is utilized or consumed during the execution of a process

Note 1 to entry: Includes diverse entities such as funding, personnel, facilities, capital equipment, tools, and utilities

such as power, water, fuel and communication infrastructures.

Note 2 to entry: Resources include those that are reusable, renewable or consumable.

**4.1.39**

**retirement**

withdrawal of active support by the operation and maintenance organization, partial or total replacement by a new system, or installation of an upgraded system

**4.1.40**

**risk**

effect of uncertainty on objectives

|  |  |
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| Note 1 to entry: | An effect is a deviation from the expected — positive or negative. A positive effect is also known as |
| an opportunity. |  |
| Note 2 to--entry: | Objectives can have different aspects (such as financial, health and safety, and environmental goals) |
| and can apply at different levels (such as strategic, organization-wide, project, product and process). | |
| -`-`,,`,,,`,``,,,`,`,``,``,,,,,,` | Risk is often characterized by reference to potential events and consequences, or a combination of |
| Note 3 to entry: |
| these. |  |
| Note 4 to entry: | Risk is often expressed in terms of a combination of the consequences of an event (including changes |
| ---`,,`,,`,`,,` |  |
| in circumstances) and the associated likelihood of occurrence. | |
| Note 5 to entry: | Uncertainty is the state, even partial, of deficiency of information related to understanding or |

knowledge of an event, its consequence, or likelihood.

[SOURCE: ISO Guide 73:2009, definition 1.1]

**4.1.41**

**security**

protection against intentional subversion or forced failure. A composite of four attributes – confidentiality, integrity, availability, and accountability – plus aspects of a fifth, usability, all of which have the related issue of their assurance.

[SOURCE: NATO AEP-67]

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**4.1.42**

**service**

performance of activities, work, or duties

Note 1 to entry:

A service is self contained, coherent, discrete, and can be composed of other services.

Note 2 to entry:

A service is generally an intangible product.

**4.1.43**

**stage**

period within the life cycle of an entity that relates to the state of its description or realization

Note 1 to entry: As used in this International Standard, stages relate to major progress and achievement milestones of the entity through its life cycle.

Note 2 to entry:

Stages often overlap.

**4.1.44**

**stakeholder**

individual or organization having a right, share, claim, or interest in a system or in its possession of characteristics that meet their needs and expectations

EXAMPLE End users, end user organizations, supporters, developers, producers, trainers, maintainers, disposers, acquirers, supplier organizations and regulatory bodies.

Note 1 to entry:

Some stakeholders can have interests that oppose each other or oppose the system.

**4.1.45**

**supplier**

organization or an individual that enters into an agreement with the acquirer for the supply of a product or service

Note 1 to entry:

Other terms commonly used for supplier are contractor, producer, seller or vendor.

Note 2 to entry:

The acquirer and the supplier sometimes are part of the same organization.

**4.1.46**

**system**

combination of interacting elements organized to achieve one or more stated purposes

Note 1 to entry:

A system is sometimes considered as a product or as the services it provides.

Note 2 to entry: In practice, the interpretation of its meaning is frequently clarified by the use of an associative noun,

e.g., aircraft system. Alternatively, the word “system” is substituted simply by a context-dependent synonym, e.g., aircraft, though this potentially obscures a system principles perspective.

Note 3 to entry: A complete system includes all of the associated equipment, facilities, material, computer programs, firmware, technical documentation, services and personnel required for operations and support to the degree necessary

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| for self-sufficient use in its intended environment. | | | |  |  |  | --- |
| **4.1.47** |  |  |  |  |  |  | `-`,,`,,`,`,,` |
| **system element** | |  |  |  |  |  | - |
| procedures (e.g., operator instructions), facilities, materials, and naturally occurring entities or any combination. | | | | | | | `,,`,,,`,``,,,`,`,``,``,,,,,,` |
| member of a set of elements that constitute a system | | | | |  |  |  |
| EXAMPLE | Hardware, software, | data, | humans, | processes (e.g., | processes for providing | service to | users), |
|  |  |  |  |  |  |  | -- |
| Note 1 to entry: | A system element | is a | discrete | part of a system | that can be implemented | to fulfill specified | |
| requirements. |  |  |  |  |  |  |  |

**4.1.48**

**system-of-interest**

system whose life cycle is under consideration in the context of this International Standard

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**4.1.49**

**systems engineering**

interdisciplinary approach governing the total technical and managerial effort required to transform a set of stakeholder needs, expectations, and constraints into a solution and to support that solution throughout its life

**4.1.50**

**task**

required, recommended, or permissible action, intended to contribute to the achievement of one or more outcomes of a process

**4.1.51**

**trade-off**

decision-making actions that select from various requirements and alternative solutions on the basis of net benefit to the stakeholders

**4.1.52**

**user**

individual or group that interacts with a system or benefits from a system during its utilization

Note 1 to entry: The role of user and the role of operator are sometimes vested, simultaneously or sequentially, in the same individual or organization.

[SOURCE: ISO/IEC 25010:2011]

**4.1.53**

**validation**

confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: A system is able to accomplish its intended use, goals and objectives (i.e., meet stakeholder requirements) in the intended operational environment. The right system was built.

[SOURCE: ISO 9000:2005, modified – Note 1 to entry has been added]

**4.1.54**

**verification**

confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: Verification is a set of activities that compares a system or system element against the required characteristics. This includes, but is not limited to, specified requirements, design description and the system itself. The system was built right.

[SOURCE: ISO 9000:2005, modified – Note 1 to entry has been added]

**4.2 Abbreviated terms**

CM

CCB

COTS

|  |  |
| --- | --- |
| FCA | -- |
| -`-`,,`,,,`,``,,,`,`,``,``,,,,,,` |
| PCA |
| NDI |  |
| QA | `,,`,,`,`,,` |
|  | --- |
| SDP |  |

Configuration Management

Configuration Control Board

Commercial-Off-The-Shelf

Functional Configuration Audit

Non-developmental Items

Physical Configuration Audit

Quality Assurance

Software Development Plan

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SEMP Systems Engineering Management Plan

SOI System of Interest

SoS System of Systems

**5** **Key concepts and application of this International Standard**

**5.1 Introduction**

This clause is included to highlight and to help explain essential concepts on which this International Standard is based. Further elaboration of these concepts can be found in the ISO/IEC TR 24748-1 (IEEE Std 24748-1-2011) and 24748-2 (IEEE Std 24748-2-2012) guides on the application of life cycle management.

**5.2 System concepts**

**5.2.1** **Systems**

The systems considered in this International Standard are man-made, created and utilized to provide products or services in defined environments for the benefit of users and other stakeholders. These systems may be configured with one or more of the following system elements: hardware, software, data, humans, processes (e.g., processes for providing service to users), procedures (e.g., operator instructions), facilities, materials and naturally occurring entities . As viewed by the user, they are thought of as products or services.

The perception and definition of a particular system, its architecture and its system elements depend on a stakeholder's interests and responsibilities. One stakeholder's system-of-interest can be viewed as a system element in another stakeholder's system-of-interest. Furthermore, a system-of-interest can be viewed as being part of the environment for another stakeholder's system-of-interest.

The following are key points regarding the characteristics of the systems-of-interest:

1. defined boundaries encapsulate meaningful needs and practical solutions;
2. there is a hierarchical or other relationship between system elements;
3. an entity at any level in the system-of-interest can be viewed as a system;
4. a system comprises an integrated, defined set of subordinate system elements;
5. humans can be viewed as both users external to a system and as system elements (i.e., operators) within a system;
6. a system can be viewed in isolation as an entity, i.e., a product; or as a collection of functions capable of interacting with its surrounding environment, i.e., a set of services.

Whatever the boundaries chosen to define the system, the concepts in this International Standard are generic and permit a practitioner to correlate or adapt individual instances of life cycles to its system principles.

**5.2.2** **System structure**

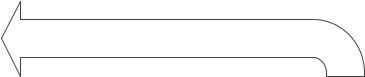
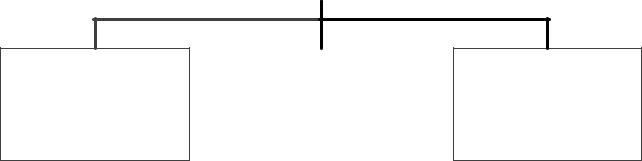
The system life cycle processes in this International Standard are described in relation to a system (see Figure 1) that is composed of a set of interacting system elements, each of which can be implemented to fulfill its respective specified requirements. Responsibility for the implementation of any system element may therefore be delegated to another party through an agreement.

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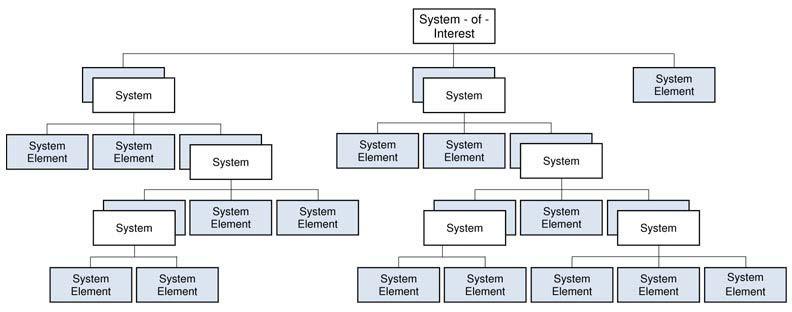
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**Figure 1 — System and system element relationship**

The relationship between the system and its complete set of system elements can typically be represented in a hierarchy for the simplest of systems-of-interest. For more complex systems-of-interest, a prospective system element may itself need to be considered as a system (that in turn is comprised of system elements) before a complete set of system elements can be defined with confidence (see Figure 2). In this manner, the appropriate system life cycle processes are applied recursively to a system-of-interest to resolve its structure to the point where understandable and manageable system elements can be implemented (made, bought, or reused). While Figures 1 and 2 imply a hierarchical relationship, in reality there are an increasing number of systems that, from one or more aspects, are not hierarchical, such as networks and other distributed systems. Annex G discusses the concept of a system of systems (SoS).



**Figure 2 — System-of-interest structure**

**5.2.3** **Enabling systems**

Throughout the life cycle of a system-of-interest, essential services are required from systems that are not directly a part of the operational environment of the system-of interest, e.g., mass-production system, training system, maintenance system. Each of these systems enables a part, e.g., a stage of the life cycle of the system- of-interest to be conducted. Termed "enabling systems", they facilitate progression of the system-of-interest through its life cycle.

The relationship between the services delivered to the operational environment by the system-of-interest and the services delivered by the enabling systems to the system-of-interest are shown in Figure 3. Enabling systems can be seen to contribute indirectly to the services provided by the system-of-interest. The interrelationships between the system-of-interest and the enabling systems can be bi-directional or a one-way relationship. In addition to interacting with enabling systems, the system-of-interest may also interact with other systems in the operating environment, shown as Systems A, B, and C. Requirements for interfaces with enabling systems and other systems in the operational environment will need to be included in the requirements for the system-of-interest.

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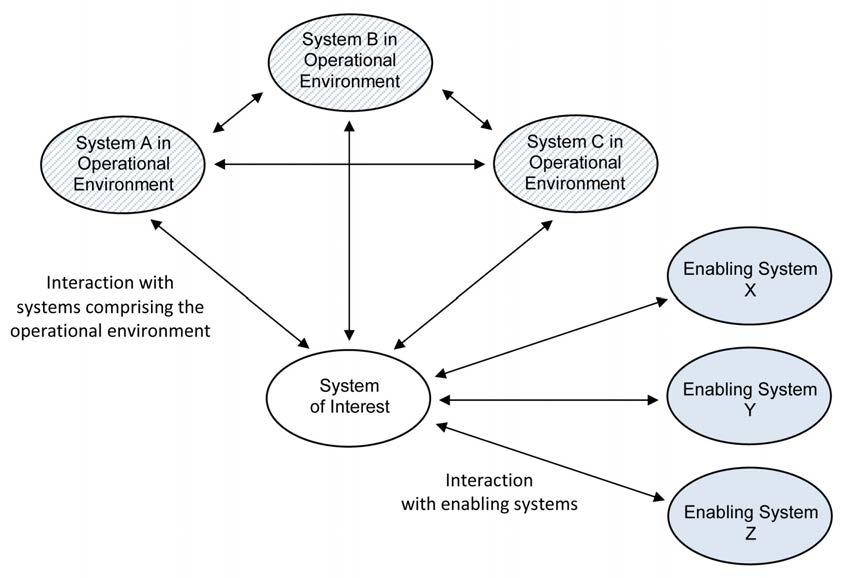
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**Figure 3 — System-of-interest, its operational environment and enabling systems**

During a stage in the system life cycle, the relevant enabling systems and the system-of-interest are considered together. Since they are interdependent, they can also be viewed as a system. When a suitable enabling system does not already exist, the project that is responsible for the system-of-interest can also be directly responsible for creating and using the enabling system. Creating the enabling systems can be viewed as a separate project and subsequently another system-of-interest.

Further elaboration of these concepts can be found in the ISO/IEC/IEEE TR 24748 guides, on the application of life cycle processes.

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**5.3 Organization and project concepts**

**5.3.1** **Organizations**

When an organization, as a whole or a part, enters into an agreement, it is sometimes called a “party” to the agreement. Parties may be from the same organization or from separate organizations. An organization may be as small as a single individual, if the individual is assigned responsibilities and authorities.

In informal terms, the organization that is responsible for executing a process is sometimes referred to by the name of that process. For example, the organization executing the Acquisition process is sometimes called the “acquirer”. Other examples include supplier, implementer, maintainer, and operator.

A few other terms are applied to organizations in this standard: "user" can be the organization that benefits from the utilization of the product or service; "customer" refers to the user and acquirer collectively; and "stakeholder" refers to an individual or organization with an interest in the system.

The processes and organizations are only related functionally. The standard does not dictate or imply a structure for an organization, nor does it specify that particular processes are to be executed by particular parts of the organization. It is the responsibility of the organization that implements the standard to define a suitable structure for the organization and assign appropriate roles for the execution of processes.

The processes in this standard form a comprehensive set to serve various organizations. An organization, small or large, depending on its business purpose or its acquisition strategy, can select an appropriate set of the processes (and associated activities and tasks) to fulfill that purpose. An organization may perform one process or more than one process.

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This standard is intended to be applied by an organization internally or externally by two or more organizations. When applied internally, the two agreeing parties typically act under the terms of an agreement that may vary in formality under different circumstances. When applied externally, the two agreeing parties typically act under the terms of a contract. This standard uses the term “agreement” to apply to either situation.

For the purpose of this standard, any project is assumed to be conducted within the context of an organization. This is important because a project is dependent upon various outcomes produced by the business processes of the organization, e.g., employees to staff the project and facilities to house the project. For this purpose, this standard provides a set of “Organizational Project-Enabling” processes. These processes are not assumed to be adequate to operate a business; instead the processes, considered as a collection, are intended to state the minimum set of dependencies that the project places upon the organization.

**5.3.2** **Organization and project-level adoption**

Modern businesses strive to develop a robust set of life cycle processes that are applied repeatedly to the projects of the business. Therefore, this standard is intended to be useful for adoption at either the organization level or at the project level. An organization would adopt the standard and supplement it with appropriate procedures, practices, tools and policies. A project of the organization would typically conform to the organization's processes rather than conform directly to this standard.

In some cases, projects may be executed by an organization that does not have an appropriate set of processes adopted at the organizational level. Such a project may apply the provisions of this standard directly to the project.

**5.4 Life cycle concepts**

**5.4.1 System life cycle model**

Every system has a life cycle. A life cycle can be described using an abstract functional model that represents the conceptualization of a need for the system, its realization, utilization, evolution and disposal.

A system progresses through its life cycle as the result of actions, performed and managed by people in organizations, using processes for execution of these actions. The detail in the life cycle model is expressed in terms of these processes, their outcomes, relationships and sequence. This International Standard does not prescribe any particular life cycle model. Instead it defines a set of processes, termed life cycle processes, that can be used in the definition of the system's life cycle. Also, this International Standard does not prescribe any particular sequence of processes within the life cycle model. The sequence of the processes is determined by project objectives and by selection of the system life cycle model.

**5.4.2** **System life cycle stages**

Life cycles vary according to the nature, purpose, use and prevailing circumstances of the system. Each stage has a distinct purpose and contribution to the whole life cycle and is considered when planning and executing the system life cycle.

The stages represent the major life cycle periods associated with a system and they relate to the state of the system description or the system itself. The stages describe the major progress and achievement milestones of the system through its life cycle. They give rise to the primary decision gates of the life cycle. These decision gates are used by organizations to understand and manage the inherent uncertainties and risks associated with costs, schedule and functionality when creating or utilizing a system. The stages thus provide organizations with a framework within which organization management has high-level visibility and control of project and technical processes.

Per ISO/IEC TR 24748-1 (IEEE Std 24748-1-2011), the typical system life cycle stages include concept, development, production, utilization, support, and retirement.

Organizations employ stages differently to satisfy contrasting business and risk mitigation strategies. Using stages concurrently and in different orders can lead to life cycle forms with distinctly different characteristics.

Further elaboration of these concepts can be found in the ISO/IEC/IEEE TR 24748 guides, on the application of life cycle management.

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**5.5 Process concepts**

**5.5.1** **Criteria for processes**

The determination of the life cycle processes in this International Standard is based upon three basic principles:

Each life cycle process has strong relationships among its outcomes, activities and tasks. The dependencies among the processes are reduced to the greatest feasible extent.

A process is capable of execution by a single organization in the life cycle.

**5.5.2** **Description of processes**

Each process of this standard is described in terms of the following attributes:

The title conveys the scope of the process as a whole;

The purpose describes the goals of performing the process;

The outcomes express the observable results expected from the successful performance of the process; The activities are sets of cohesive tasks of a process;

The tasks are requirements, recommendations, or permissible actions intended to support the achievement of the outcomes.

Additional detail regarding this form of process description can be found in ISO/IEC TR 24774.

**5.5.3** **General characteristics of processes**

In addition to the basic attributes described in the previous subclause, processes may be characterized by other attributes common to all processes. ISO/IEC 15504-2 identifies common process attributes that characterize six levels of achievement within a measurement framework for process capability. Annex C of this International Standard includes the list of process attributes that contribute to the achievement of higher levels of process capability as defined in ISO/IEC 15504-2

**5.5.4** **Tailoring**

Annex A, which is normative, defines the basic activities needed to perform tailoring of this International Standard. Note that tailoring may diminish the perceived value of a claim of conformance to this standard. This is because it is difficult for other organizations to understand the extent to which tailoring may have deleted desirable provisions. An organization asserting a single-party claim of conformance to this standard may find it advantageous to claim full conformance to a smaller list of processes rather than tailored conformance to a larger list of processes.

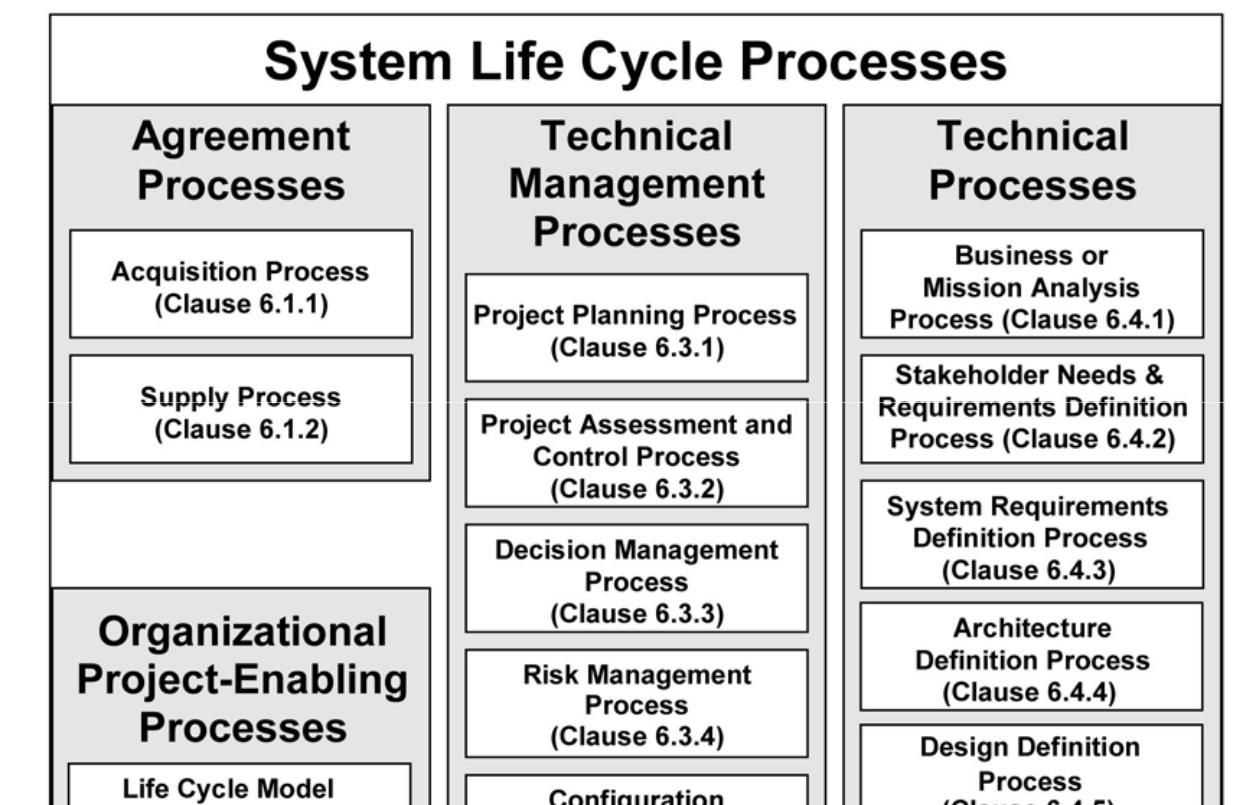
**5.6 Processes in this standard**

**5.6.1** **Introduction**

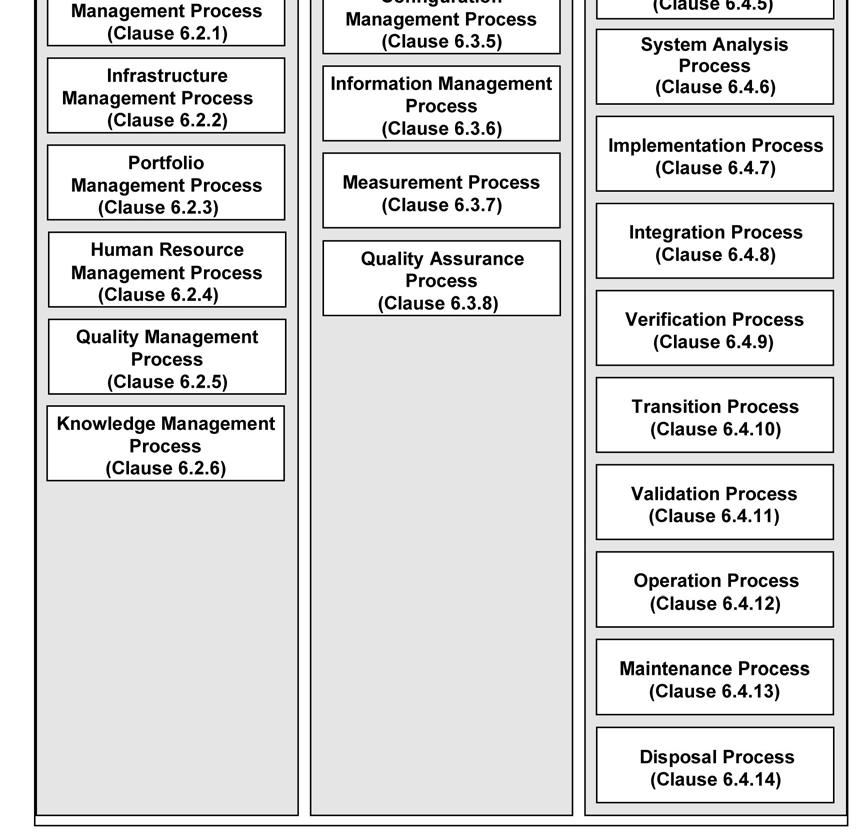
This International Standard groups the activities that can be performed during the life cycle of a system into four process groups. Each of the life cycle processes within those groups is described in terms of its purpose and desired outcomes and lists activities and tasks to be performed to achieve those outcomes. The four process groups and the processes included in each group are depicted in Figure 4. The processes described in this International Standard are not intended to preclude or discourage the use of additional processes that organizations find useful. A description of each process group is provided in the four subclauses that follow.

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**Figure 4 — System life cycle processes**

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**5.6.2** **Agreement processes**

Organizations are producers and users of systems. One organization (acting as an acquirer) can task another (acting as a supplier) for products or services. This is achieved using agreements.

Generally, organizations act simultaneously or successively as both acquirers and suppliers of systems. The Agreement Processes can be used with less formality when the acquirer and the supplier are in the same organization. Similarly, they can be used within the organization to agree on the respective responsibilities of organization, project and technical functions. Figure 4 lists the processes contained in this process group.

**5.6.3** **Organizational project-enabling processes**

The Organizational Project-Enabling Processes are concerned with providing the resources needed to enable the project to meet the needs and expectations of the organization’s interested parties. The Organizational Project-Enabling Processes are typically concerned at a strategic level with the management and improvement of the organization’s business or undertaking, with the provision and deployment of resources and assets, and with its management of risks in competitive or uncertain situations.

The Organizational Project-Enabling Processes establish the environment in which projects are conducted. ---

The organization establishes the processes and life cycle models to be used by projects; establishes,`,,`,,`,`,,` redirects, or cancels projects; provides resources required, including human and financial; and sets and

monitors the quality measures for systems and other deliverables that are developed by projects for internal -

and external customers. `-`,,`,,,`,``,,,`,`,``,``,,,,,,`

The Organizational Project-Enabling Processes create a strong business image for many organizations and imply commercial and profit-making motives. Nevertheless, the Organizational Project-Enabling Processes are equally relevant to non-profit organizations, since they are also accountable to stakeholders, are-- responsible for resources and encounter risk in their undertakings. This International Standard can be applied to non-profit organizations as well as to profit-making organizations. Figure 4 lists the processes contained in this process group.

**5.6.4** **Technical management processes**

The Technical Management Processes are concerned with managing the resources and assets allocated by organization management and with applying them to fulfill the agreements into which the organization or organizations enter. The Technical Management Processes relate to the technical effort of projects, in particular to planning in terms of cost, timescales and achievements, to the checking of actions to help ensure that they comply with plans and performance criteria, and to the identification and selection of corrective actions that recover shortfalls in progress and achievement. They are used to establish and perform technical plans for the project, manage information across the technical team, assess technical progress against the plans for the system products or services, control technical tasks through to completion, and to aid in the decision-making process.

NOTE 1 Technical management is ‘the application of technical and administrative resources to plan, organize and control engineering functions’ (ISO/IEC/IEEE 24765:2010).

Typically several projects will co-exist in any one organization. The Technical Management Processes can be employed at a corporate level to meet internal needs. Figure 4 lists the processes contained in this process group.

NOTE 2 Technical Management Processes are applied during the performance of each Technical Process.

**5.6.5** **Technical processes**

The Technical Processes are concerned with technical actions throughout the life cycle. Technical Processes transform the needs of stakeholders into a product and service. By applying that product or operating that service, technical processes provide sustainable performance, when and where needed, in order to meet the stakeholder requirements and achieve customer satisfaction. The Technical Processes are applied in order to create and use a system, whether it is in the form of a model or is a finished product. The Technical Processes apply at any level in a hierarchy of system structure and at any stage in the life cycle. Figure 4 lists the processes contained in this process group.

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**5.7 Process application**

The life cycle processes defined in this International Standard can be used by any organization when acquiring, using, creating, or supplying a system. They can be applied at any level in a system’s hierarchy and at any stage in the life cycle.

The functions these processes perform are defined in terms of specific purposes, outcomes and the set of activities and tasks that constitute the process.

Each life cycle process in Figure 4 can be invoked, as required, at any time throughout the life cycle. The order that the processes are presented in this standard does not imply any prescriptive order in their use. However, sequential relationships are introduced by the definition of a life cycle model. The detailed purpose and timing of use of these processes throughout the life cycle are influenced by multiple factors, including social, trading, organizational and technical considerations, each of which can vary during the life of a system. An individual system life cycle is thus a complex system of processes that will normally possess concurrent, iterative, recursive and time dependent characteristics.

Concurrent use of processes can exist within a project (e.g., when design actions and preparatory actions for building a system are performed at the same time), and between projects (e.g., when system elements are designed at the same time under different project responsibilities).

When the application of the same process or set of processes is repeated on the same system, the application is referred to as iterative. The iterative use of processes is important for the progressive refinement of process outputs, e.g., the interaction between successive verification actions and integration actions can incrementally build confidence in the conformance of the product. Iteration is not only appropriate but also expected. New information is created by the application of a process or set of processes. Typically this information takes the form of questions with respect to requirements, analyzed risks or opportunities. Such questions should be resolved before completing the activities of a process or set of processes.

The recursive use of processes, i.e., the repeated application of the same process or set of processes applied to successive levels of system elements in a system’s structure, is a key aspect of the application of this International Standard. The outputs of processes at any level, whether information, artifacts or services, are inputs to the processes used at the level below (e.g., during top down design) or level above (e.g., during system realization). The outcomes from one application are used as inputs to the next lower (or higher) system in the system structure to arrive at a more detailed or mature set of outcomes. Such an approach adds value to successive systems in the system structure.

The changing nature of the influences on the system (e.g., operational environment changes, new opportunities for system element implementation, modified structure and responsibilities in organizations) requires continual review of the selection and timing of process use. Process use in the life cycle can be dynamic, responding to the many external influences on the system. The life cycle approach also allows for incorporating the changes in the next stage. The life cycle stages assist the planning, execution and management of life cycle processes in the face of this complexity in life cycles by providing comprehensible and recognizable high-level purpose and structure. The set of processes within a life cycle stage are applied with the common goal of satisfying the exit criteria for that stage or the entry criteria of the formal progress reviews within that stage.

The discussion in this section on iterative and recursive use of the system life cycle processes is not meant to imply any specific hierarchical, vertical, or horizontal structure for the system-of-interest, enabling system, organization, or project.

Where justified by product quality risks, detailed descriptions of process instances in the context of the specific product may also be created. Instantiation of processes involves identifying specific success criteria for a process instance, derived from the product requirements, and identifying the specific activities and tasks needed to achieve the success criteria, derived from the activities and tasks identified in this standard. Creating detailed descriptions of process instances enables better management of product quality risks by establishing the link between the process and the specific product requirements.

Further elaboration of these concepts can be found in the ISO/IEC/IEEE TR 24748 guides, on the application of life cycle processes.

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**5.8 Process reference model**

Annex C defines a Process Reference Model (PRM) at a level of abstraction higher than that of the detailed requirements contained in Clause 6 of this International Standard. The PRM is applicable to an organization that is assessing its processes in order to determine the capability of these processes. The purpose and outcomes are a statement of the goals of the performance of each process. This statement of goals permits assessment of the effectiveness of the processes in ways other than simple conformity assessment.

NOTE In this International Standard, the term “Process Reference Model” is used with the same meaning as ISO/IEC

15504-2.

**6** **System life cycle processes**

**6.1 Agreement processes**

This subclause specifies the requirements for the establishment of agreements with organizational entities external and internal to the organization.

The Agreement Processes consist of the following:

1. Acquisition process – used by organizations for acquiring products or services;
2. Supply process – used by organizations for supplying products or services.

These processes define the activities necessary to establish an agreement between two organizations. If the Acquisition process is invoked, it provides the means for conducting business with a supplier. This may include products that are supplied for use as an operational system, services in support of operational activities, or elements of a system being provided by a supplier. If the Supply process is invoked, it provides the means for an agreement in which the result is a product or service that is provided to the acquirer.

NOTE Security is an increasing concern in systems engineering. See ISO/IEC 27036, *Security techniques —* *Information security for supplier relationships*, for requirements and guidance for suppliers and acquirers on how to secureinformation in supplier relationships. Specific aspects of information security supplier relationships are addressed in Parts 3 and Part 4.

**6.1.1** **Acquisition process**

**6.1.1.1** **Purpose**

The purpose of the Acquisition process is to obtain a product or service in accordance with the acquirer's requirements.

NOTE As part of this process, the agreement is modified when a change request is agreed to by both the acquirer and supplier.

**6.1.1.2 Outcomes**

As a result of the successful implementation of the Acquisition process:

1. A request for supply is prepared.
2. One or more suppliers are selected.
3. An agreement is established between the acquirer and supplier.
4. A product or service complying with the agreement is accepted.
5. Acquirer obligations defined in the agreement are satisfied.

**6.1.1.3** **Activities and tasks**

The acquirer shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Acquisition process.

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NOTE The activities and resulting agreement from this process often apply to suppliers in the supply chain, including subcontracted suppliers.

a) **Prepare for the acquisition.** This activity consists of the following tasks:

1. Define a strategy for how the acquisition will be conducted.

NOTE This strategy describes or references the life cycle model, risks and issues mitigation, a schedule of milestones, and selection criteria if the supplier is external to the acquiring organization. It also includes key drivers and characteristics of the acquisition, such as responsibilities and liabilities; specific models, methods, or processes; level of criticality; formality; and priority of relevant trade factors.

1. Prepare a request for the supply of a product or service that includes the requirements.

NOTE 1 If a supplier is external to the organization, then the request includes the business practices with which a supplier is expected to comply and the criteria for selecting a supplier.

NOTE 2 A definition of requirements is provided to one or more suppliers. The requirements are the stakeholder or the system requirements, depending on the type of acquisition approach, through the associated requirements definition process.

NOTE 3 The acquirer develops the requirements by itself or retains a supplier to develop them. If the acquirer retains a supplier to develop requirements, the acquirer retains approval authority for the requirements developed by the supplier.

1. **Advertise the acquisition and select the supplier.** This activity consists of the following tasks:
   1. Communicate the request for the supply of a product or service to potential suppliers.
   2. Select one or more suppliers.

NOTE To obtain competitive solicitations, proposals to supply are evaluated and compared against the selection criteria and ranked. The justification for rating each proposal is declared and suppliers are informed why they were or were not selected.

c) **Establish and maintain an agreement.** This activity consists of the following tasks:

NOTE Project cost, schedule, and performance are monitored through the Project Assessment and Control process. Any identified issues that require agreement modifications are referred to this activity. Any proposals for changes to system elements or information are controlled through the Change Management activity of the Configuration Management process.

1. Develop an agreement with the supplier that includes acceptance criteria.

NOTE 1 This agreement ranges in formality from a written contract to a verbal agreement. Appropriate to the level of formality, the agreement establishes requirements, development and delivery milestones, verification, validation and acceptance conditions, exception-handling procedures, agreement change management procedures and payment schedules, so that both parties of the agreement understand the basis for executing the agreement. Rights and restrictions associated with technical data and intellectual property are noted in the agreement. Details are discussed and changed during negotiation, after which the acquirer and supplier accept the terms of an agreement and the agreement commences. For a written contract, this occurs when the contract is signed.

NOTE 2 The agreement identifies any process requirements that need to be imposed on participating subcontractors, such as configuration management requirements, reporting of risks, and reporting of measures and measurement analysis.

1. Identify necessary changes to the agreement.

NOTE In requesting a change to the agreement, the acquirer or the supplier details its specifications, rationale, and background.

1. Evaluate impact of changes on the agreement.

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NOTE Any change is investigated for impacts to project plans, schedule, cost, technical capability, and quality. A change can be handled within the existing agreement, can require a modification to the agreement, or can require a new agreement.

1. Negotiate the agreement with the supplier.

NOTE Agreement terms are negotiated between the acquirer and supplier. Negotiation occurs for the initial agreement, and as required for any changes. Changed agreements are based on the required change and identified impacts.

1. Update the agreement with the supplier, as necessary.

NOTE The result of the agreement modification is incorporated into the project plans and communicated to all affected parties.

1. **Monitor the agreement.** This activity consists of the following tasks:
   1. Assess the execution of the agreement.

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NOTE This includes confirmation that all parties are meeting their responsibilities according to the agreement. The Project Assessment and Control process is used to evaluate projected cost, schedule, performance, and the impact of undesirable outcomes on the organization. This information is combined with other assessments of the execution of the terms of the agreement.

1. Provide data needed by the supplier and resolve issues in a timely manner.

**Accept the product or service.** This activity consists of the following tasks:

1. Confirm that the delivered product or service complies with the agreement.

NOTE Exceptions that arise during the conduct of the agreement or with the delivered product or service are resolved according to the procedures established in the agreement.

1. Provide payment or other agreed consideration.
2. Accept the product or service from the supplier, or other party, as directed by the agreement.
3. Close the agreement.

NOTE The project is closed by the Portfolio Management process.

**6.1.2** **Supply process**

**6.1.2.1** **Purpose**

The purpose of the Supply process is to provide an acquirer with a product or service that meets agreed requirements.

NOTE As part of this process, the agreement is modified when a change request is agreed to by both the acquirer and supplier.

**6.1.2.2 Outcomes**

As a result of the successful implementation of the Supply process:

1. An acquirer for a product or service is identified.
2. A response to the acquirer's request is produced.
3. An agreement is established between the acquirer and supplier.
4. A product or service is provided.
5. Supplier obligations defined in the agreement are satisfied.

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1. Responsibility for the acquired product or service, as directed by the agreement, is transferred.

**6.1.2.3** **Activities and tasks**

The supplier shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Supply process.

a) **Prepare for the supply.** This activity consists of the following tasks:

1. Determine the existence and identity of an acquirer who has a need for a product or service.

NOTE This is often generated through the Business or Mission Analysis process. For a product or service developed for consumers, an agent, e.g., a marketing function within the supplier organization, often represents the acquirer.

1. Define a supply strategy.

NOTE This strategy describes or references the life cycle model, risks and issues mitigation, and a schedule of milestones. It also includes key drivers and characteristics of the acquisition such as responsibilities and liabilities; specific models; methods or processes; level of criticality; formality; and priority of relevant trade factors.

1. **Respond to a tender.** This activity consists of the following tasks:
   1. Evaluate a request for the supply of a product or service to determine feasibility and how to respond.
   2. Prepare a response that satisfies the solicitation.
2. **Establish and maintain an agreement.** This activity consists of the following tasks:
   1. Negotiate an agreement with the acquirer that includes acceptance criteria.

NOTE This agreement ranges in formality from a written contract to a verbal agreement. The Supplier confirms that the requirements, delivery milestones and acceptance conditions are achievable, that exception handling and agreement change management procedures and payment schedules are acceptable, and that they establish a basis for executing the agreement without unnecessary risks. Any issues are discussed and resolved during negotiation, after which the acquirer and supplier accept the terms of an agreement and the agreement commences. For a contract, this occurs when the contract is signed.

1. Identify necessary changes to the agreement.

NOTE In requesting a change to the agreement, the acquirer or the supplier details its specifications, rationale, and background.

1. Evaluate impact of changes on the agreement.

NOTE Any change is investigated for impacts to project plans, schedule, cost, technical capability, or quality. A change can be handled within the existing agreement, can require a modification to the agreement, or can require a new agreement.

1. Negotiate the agreement with the acquirer.

NOTE Changes to any agreement terms are negotiated between the supplier and acquirer. This includes changes due to changing market context. Negotiation occurs for the initial agreement, and as required for any changes. Changed agreements are based on the required change and identified impacts.

1. Update the agreement with the acquirer, as necessary.

NOTE The result of the agreement modification is incorporated into the project plans and communicated to all affected parties.

d) **Execute the agreement.** This activity consists of the following tasks:

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1. Execute the agreement according to the established project plans.

NOTE A supplier sometimes adopts, or agrees to use, acquirer processes.

1. Assess the execution of the agreement.

NOTE This includes confirmation that all parties are meeting their responsibilities according to the agreement. The Project Assessment and Control process is used to evaluate projected cost, schedule, performance, and the impact of undesirable outcomes on the organization. The change management activity of the Configuration Management process is used to control changes to the system elements. This information is combined with other assessments of the execution of the terms of the agreement.

1. **Deliver and support the product or service.** This activity consists of the following tasks:
   1. Deliver the product or service in accordance with the agreement criteria.
   2. Provide assistance to the acquirer in support of the delivered product or service, per the agreement.
   3. Accept and acknowledge payment or other agreed consideration.
   4. Transfer the product or service to the acquirer, or other party, as directed by the agreement.
   5. Close the agreement.

NOTE The project is closed by the Portfolio Management process.

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**6.2 Organizational project-enabling processes**

The Organizational Project-Enabling Processes help ensure the organization’s capability to acquire and supply products or services through the initiation, support and control of projects. These processes provide resources and infrastructure necessary to support projects and help ensure the satisfaction of organizational objectives and established agreements. They are not intended to be a comprehensive set of business processes that enable strategic management of the organization's business.

The Organizational Project-Enabling Processes consist of the following:

1. Life Cycle Model Management process;
2. Infrastructure Management process;
3. Portfolio Management process;
4. Human Resource Management process;
5. Quality Management process;
6. Knowledge Management process.

**6.2.1** **Life cycle model management process**

**6.2.1.1** **Purpose**

The purpose of the Life Cycle Model Management process is to define, maintain, and assure availability of policies, life cycle processes, life cycle models, and procedures for use by the organization with respect to the scope of this International Standard.

This process provides life cycle policies, processes, models, and procedures that are consistent with the organization's objectives, that are defined, adapted, improved and maintained to support individual project needs within the context of the organization, and that are capable of being applied using effective, proven methods and tools.

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**6.2.1.2 Outcomes**

As a result of the successful implementation of the Life Cycle Model Management process:

1. Organizational policies and procedures for the management and deployment of life cycle models and processes are established.
2. Responsibility, accountability, and authority within life cycle policies, processes, models, and procedures are defined.
3. Life cycle models and processes for use by the organization are assessed.
4. Prioritized process, model, and procedure improvements are implemented.

**6.2.1.3** **Activities and tasks**

The organization shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Life Cycle Model Management process.

a) **Establish the process.** This activity consists of the following tasks:

NOTE The detail of the life cycle implementation within a project is dependent upon the complexity of the work, the

methods used, and the skills and training of personnel involved in performing the work. A project tailors policies, processes, models, and procedures according to its requirements and needs, while maintaining alignment with regulations and organizational policies. Annex A contains information on tailoring.

1. Establish policies and procedures for process management and deployment that are consistent with organizational strategies.
2. Establish the processes that implement the requirements of this international standard and that are consistent with organizational strategies.
3. Define the roles, responsibilities, accountabilities, and authorities to facilitate implementation of processes and the strategic management of life cycles.
4. Define business criteria that control progression through the life cycle.

NOTE The decision-making criteria regarding entering and exiting each life cycle stage and key milestones are established. These are sometimes expressed in terms of business achievement.

1. Establish standard life cycle models for the organization that are comprised of stages, and define the purpose and outcomes for each stage.

NOTE The life cycle model comprises one or more stage models, as needed. It is assembled as a sequence of stages that overlap or iterate, as appropriate for the system-of-interest's scope, magnitude, complexity, changing needs and opportunities. Stages are illustrated in the ISO/IEC TR 24748 -1 (IEEE Std 24748-1-2011) guide using a commonly encountered example of life cycle stages. Specific examples for systems are provided in ISO/IEC TR 24748-2 (IEEE Std 24748-2-2012)*.* The life cycle processes and activities are selected, tailored as appropriate and employed in a stage to fulfill the purpose and outcomes of that stage.

b) **Assess the process.** This activity consists of the following tasks:

NOTE ISO/IEC 15504 provides a more detailed set of process assessment activities and tasks that are aligned with the tasks shown below.

1. Monitor process execution across the organization.

NOTE This includes the analysis of process measures and review of trends with respect to business criteria, feedback from the projects regarding the effectiveness and efficiency of the processes, and monitoring execution according to regulations and organizational policies.

1. Conduct periodic reviews of the life cycle models used by the projects.

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NOTE This includes confirming the continuing suitability, adequacy and effectiveness of the life cycle models used by the projects and making improvements as appropriate. This includes the stages, processes and achievement criteria that control progression through the life cycle.

* 1. Identify improvement opportunities from assessment results.

1. **Improve the process.** This activity consists of the following tasks:
   1. Prioritize and plan improvement opportunities.
   2. Implement improvement opportunities and inform relevant stakeholders.

NOTE Process Improvement includes improvements to any of the processes in the organization. Lessons learned are captured and available.

**6.2.2** **Infrastructure management process**

**6.2.2.1** **Purpose**

The purpose of the Infrastructure Management process is to provide the infrastructure and services to projects to support organization and project objectives throughout the life cycle.

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This process defines, provides and maintains the facilities, tools, and communications and information technology assets needed for the organization’s business with respect to the scope of this International Standard.

**6.2.2.2 Outcomes**

As a result of the successful implementation of the Infrastructure Management process:

1. The requirements for infrastructure are defined.
2. The infrastructure elements are identified and specified.
3. Infrastructure elements are developed or acquired.
4. The infrastructure is available.

**6.2.2.3** **Activities and tasks**

The organization shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Infrastructure Management process.

a) **Establish the infrastructure.** This activity consists of the following tasks:

1. Define project infrastructure requirements.

NOTE 1 Infrastructure element examples are facilities, tools, hardware, software, services, and standards.

NOTE 2 The infrastructure resource needs for the project are considered in context with other projects and resources within the organization, as well as within the policies and strategic plans of the organization. Business constraints and timelines that influence and control provision of infrastructure resources and services for the project are also evaluated. Project plans and future business needs contribute to the understanding of the resource infrastructure that is required. Physical factors (e.g., facilities), logistics needs, and human factors (including health and safety aspects) are also considered.

NOTE 3 ISO/IEC 27036, *Information security for supplier relationships*, provides guidance for addressing security of outsourced infrastructure.

1. Identify, obtain and provide infrastructure resources and services that are needed to implement and support projects.

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|  | NOTE | An inventory asset registry is often established to track infrastructure elements and support reuse. | |
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1. **Maintain the infrastructure.** This activity consists of the following tasks:
   1. Evaluate the degree to which delivered infrastructure resources satisfy project needs.
   2. Identify and provide improvements or changes to the infrastructure resources as the project requirements change.

**6.2.3** **Portfolio management process**

**6.2.3.1** **Purpose**

The purpose of the Portfolio Management process is to initiate and sustain necessary, sufficient and suitable projects in order to meet the strategic objectives of the organization.

This process commits the investment of adequate organization funding and resources, and sanctions the authorities needed to establish selected projects. It performs continued assessment of projects to confirm they justify, or can be redirected to justify, continued investment.

**6.2.3.2 Outcomes**

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| As a result of the successful implementation of the Portfolio Management process: | | |
| a) | Business venture opportunities, investments or necessities are qualified and prioritized. | |
| b) | Projects are identified. | |
| c) | Resources`,,`,,`,`,,`--- | and budgets for each project are allocated. |
| d) | Project management responsibilities, accountability, and authorities are defined. | |

e) Projects meeting agreement and stakeholder requirements are sustained.

f) Projects not meeting agreement or satisfying stakeholder requirements are redirected or terminated.

g) Projects that have completed agreements and satisfied stakeholder requirements are closed.

**6.2.3.3** **Activities and tasks**

The organization shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Portfolio Management process.

a) **Define and authorize projects.** This activity consists of the following tasks:

1. Identify potential new or modified capabilities or missions.

NOTE The organization business strategy, concept of operations, or gap or opportunity analysis is reviewed for current gaps, problems, or opportunities. A new capability or enterprise need is usually determined in the Business or Mission Analysis process, further defined in the Stakeholder Needs and Requirements Definition process, and managed through this process.

1. Prioritize, select and establish new business opportunities, ventures or undertakings.

NOTE These are usually consistent with the business strategy and action plans of the organization. The potential projects are prioritized, and thresholds established, to determine which projects will be executed. The characteristics of identified projects are often determined, including stakeholder value, risks and barriers to success, dependencies and inter-relationships, constraints, resource needs and mutual contention for resources. Each potential project is then assessed with respect to likelihood of success and cost-benefit. The Decision Management and System Analysis processes provide details on performing an analysis of alternatives.

1. Define projects, accountabilities and authorities.
2. Identify the expected goals, objectives, and outcomes of each project.

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1. Identify and allocate resources for the achievement of project goals and objectives.
2. Identify any multi-project interfaces and dependencies to be managed or supported by each project.

NOTE 1 This includes the use or reuse of enabling systems used by more than one project and the use or reuse of common system elements by more than one project.

NOTE 2 Understanding each project in the context of the enterprise architecture helps to ensure interfaces and constraints are identified.

1. Specify the project reporting requirements and review milestones that govern the execution of each project.
2. Authorize each project to commence execution of project plans.

NOTE Refer to Project Planning process for additional information on developing project plans. Project plans are most useful when developed and approved early in the project life cycle.

b) **Evaluate the portfolio of projects.** This activity consists of the following tasks:

1. Evaluate projects to confirm ongoing viability.

NOTE Viability includes:

* + 1. The project is making progress towards achieving established goals and objectives.
    2. The project is complying with project directives.
    3. The project is being conducted according to project life cycle policies, processes, and procedures.
    4. The project remains viable, as indicated by, for example, continuing need for the service, practicable product implementation, and acceptable investment benefits.
  1. Act to continue or redirect projects that are satisfactorily progressing or can be expected to progress satisfactorily by appropriate redirection.

1. **Terminate projects.** This activity consists of the following tasks:
   1. Where agreements permit, act to cancel or suspend projects whose disadvantages or risks to the organization outweigh the benefits of continued investments.
   2. After completion of the agreement for products and services, act to close the projects.

NOTE Closure is accomplished in accordance with organizational policies and procedures, and the agreement.

**6.2.4** **Human resource management process**

**6.2.4.1** **Purpose**

The purpose of the Human Resource Management process is to provide the organization with necessary human resources and to maintain their competencies, consistent with business needs.

This process provides a supply of skilled and experienced personnel qualified to perform life cycle processes to achieve organization, project, and stakeholder objectives.

**6.2.4.2 Outcomes**

As a result of the successful implementation of the Human Resource Management process:

1. Skills required by projects are identified.
2. Necessary human resources are provided to projects.

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1. Skills of personnel are developed, maintained or enhanced.
2. Conflicts in multi-project resource demands are resolved.

**6.2.4.3** **Activities and tasks**

The organization shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Human Resource Management process:

1. **Identify skills.** This activity consists of the following tasks:
   1. Identify skill needs based on current and expected projects.
   2. Identify and record skills of personnel.
2. **Develop skills.** This activity consists of the following tasks:
   1. Establish skills development strategy.

NOTE This plan includes types and levels of training, categories of personnel, schedules, personnel resource requirements, and training needs.

1. Obtain or develop training, education or mentoring resources.

NOTE These resources include training materials that are developed by the organization or external parties, training courses that are available from external suppliers, or computer based instruction.

* 1. Provide planned skill development.
  2. Maintain records of skill development.

1. **Acquire and provide skills.** This activity consists of the following tasks:

NOTE This includes: the recruitment and retention of personnel with experience levels and skills necessary to properly staff projects; staff assessment and review, e.g., their proficiency, motivation, ability to work in a team environment, as well as the need to be retrained, reassigned or reallocated.

1. Obtain qualified personnel when skill deficits are identified.

NOTE This includes using outsourced resources.

1. Maintain and manage the pool of skilled personnel necessary to staff ongoing projects.
2. Make project assignments based on project and staff-development needs.
3. Motivate personnel, e.g., through career development and reward mechanisms.
4. Control multi-project management interfaces to resolve personnel conflicts.

NOTE This includes conflicts of capacity in organizational infrastructure and supporting services and personnel resources among ongoing projects; or from project personnel being over-committed.

**6.2.5** **Quality management process**

**6.2.5.1** **Purpose**

The purpose of the Quality Management process is to assure that products, services and implementations of the quality management process meet organizational and project quality objectives and achieve customer satisfaction.

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**6.2.5.2 Outcomes**

As a result of the successful implementation of the Quality Management process:

1. Organizational quality management policies, objectives, and procedures are defined and implemented.
2. Quality evaluation criteria and methods are established.
3. Resources and information are provided to projects to support the operation and monitoring of project quality assurance activities.
4. Quality assurance evaluation results are gathered and analyzed.
5. Quality management policies and procedures are improved based upon project and organizational results.

NOTE These outcomes have been written to align with subclause 4.1, General Requirements, of ISO 9001:2008.

Refer to subclause 4.1 ISO 9001:2008 for information to establish a complete Quality Management System.

**6.2.5.3** **Activities and tasks**

The organization shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Quality Management process.

a) **Plan quality management.** This activity consists of the following tasks**:**

1. Establish quality management policies, objectives, and procedures.

NOTE 1 ISO 9001:2008 is a process model for quality management systems. ISO 9004:2009 contains guidelines for performance improvements.

NOTE 2 The policies, objectives, and procedures are based on the business strategy for customer satisfaction.

1. Define responsibilities and authority for implementation of quality management.

NOTE Resources for quality management are often assigned from distinct organizations for independence from project management.

3) Define quality evaluation criteria and methods.

4) Provide resources and information for quality management.

b) **Assess quality management.** This activity consists of the following tasks:

1) Gather and analyze quality assurance evaluation results, in accordance with the defined criteria.

2) Assess customer satisfaction.

NOTE ISO 10004:2012 contains guidelines for monitoring and measuring customer satisfaction.

* 1. Conduct periodic reviews of project Quality Assurance activities for compliance with the Quality Management policies, objectives, and procedures.
  2. Monitor the status of quality improvements on processes, products, and services.

1. **Perform quality management corrective and preventive action.** This activity consists of the followingtasks:
   1. Plan corrective actions when quality management objectives are not achieved.
   2. Plan preventive actions when there is a sufficient risk that quality management objectives will not be achieved.
   3. Monitor corrective and preventive actions to completion and inform relevant stakeholders.

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NOTE Implementation of corrective and preventive action is performed in other relevant processes, such as Life Cycle Model Management or Project Assessment and Control.

**6.2.6 Knowledge management process**

**6.2.6.1** **Purpose**

The purpose of the Knowledge Management process is to create the capability and assets that enable the organization to exploit opportunities to re-apply existing knowledge.

This encompasses knowledge, skills, and knowledge assets, including system elements.

**6.2.6.2 Outcomes**

As a result of the successful implementation of the Knowledge Management process:

1. A taxonomy for the application of knowledge assets is identified.
2. The organizational knowledge, skills, and knowledge assets are developed or acquired.
3. The organizational knowledge, skills, and knowledge assets are available.
4. Knowledge management usage data is gathered and analyzed.

**6.2.6.3** **Activities and tasks**

The organization shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Knowledge Management process:

a) **Plan knowledge management.** This activity consists of the following tasks:

1. Define the knowledge management strategy.

NOTE 1 The knowledge management strategy generally includes:

1. Identifying domains and their potential for the reapplication of knowledge.
2. Plans for obtaining and maintaining knowledge, skills, and knowledge assets for their useful life.
3. Characterization of the types of knowledge, skills, and knowledge assets to be collected and maintained.
4. Criteria for accepting, qualifying, and retiring knowledge, skills, and knowledge assets.
5. Procedures for controlling changes to the knowledge, skills, and knowledge assets.
6. Plans, mechanisms, and procedures for protection, control, and access to classified or sensitive data and information.
7. Mechanisms for storage and retrieval.

NOTE 2 Knowledge management includes knowledge shared internally within the organization and knowledge that is shared outside the organization with stakeholders, acquirers, and business partners, subject to intellectual property and non-disclosure agreements.

* 1. Identify the knowledge, skills, and knowledge assets to be managed.
  2. Identify projects that can benefit from the application of the knowledge, skills, and knowledge assets.

1. **Share knowledge and skills throughout the organization.** This activity consists of the following tasks:

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1. Establish and maintain a classification for capturing and sharing knowledge and skills across the organization.

NOTE This classification includes expert, common, and domain knowledge and skills, as well as lessons learned.

* 1. Capture or acquire knowledge and skills.
  2. Share knowledge and skills across the organization.

1. **Share knowledge assets throughout the organization.** This activity consists of the following tasks:
   1. Establish a taxonomy to organize knowledge assets.

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| NOTE 1 | The taxonomy includes the following: |  |
| i. | Definition of the boundaries of domains and their relationships to others. |  |
| ii. | Domain models capturing essential common and different features, capabilities, concepts, functions. |  |
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| iii. | An architecture for a family of systems within the domain, including their common and different features. | -`-`,,`,,`,`,,` |
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| NOTE 2 | See ISO/IEC 26550 for more information on product line models. Refer to ISO/IEC/IEEE 42010 for | |
| requirements on architecture frameworks, viewpoints, model kinds, views, and models. | | `,,`,,,`,``,,,`,`,``,``,,,,,,` |
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1. Develop or acquire knowledge assets.

NOTE Knowledge assets include system elements or their representations (e.g., reusable code libraries, reference-- architectures) architecture or design elements (e.g., architecture or design patterns), processes, criteria, or other technical information (e.g., training materials) related to domain knowledge, and lessons learned.

* + 1. Share knowledge assets across the organization.

1. **Manage knowledge, skills, and knowledge assets.** This activity consists of the following tasks:
   1. Maintain knowledge, skills, and knowledge assets.
   2. Monitor and record the use of knowledge, skills, and knowledge assets.
   3. Periodically reassess the currency of technology and market needs of the knowledge assets.

**6.3 Technical management processes**

The Technical Management Processes are used to establish and evolve plans, to execute the plans, to assess actual achievement and progress against the plans and to control execution through to fulfillment. Individual Technical Management Processes may be invoked at any time in the life cycle and at any level in a hierarchy of projects, as required by plans or unforeseen events. The Technical Management Processes are applied with a level of rigor and formality that depends on the risk and complexity of the project.

The scope of a technical management process is the technical management of a project or its products, to include the system.

NOTE This set of technical management processes are performed so that system-specific technical processes can be conducted effectively. They do not comprise a management system or a comprehensive set of processes for project management, as that is not the scope of this standard.

The Technical Management Processes consist of the following:

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|  | a) | Project Planning process; |  |
|  | b) | Project Assessment and Control process; |  |
|  | c) | Decision Management process; |  |
|  | d) | Risk Management process; |  |
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1. Configuration Management process;
2. Information Management process;
3. Measurement process;
4. Quality Assurance process.

Project Planning and Project Assessment and Control are key to all management practices. These processes establish the general approach for managing a project or a process. The other processes in this group provide a specific focused set of tasks for performing to a specialized management objective. They are all evident in the management of any undertaking, ranging from a complete organization down to a single life cycle process and its tasks. In this International Standard, the project has been chosen as the context for describing processes. The same processes can also be applied in the performance of services.

**6.3.1** **Project planning process**

**6.3.1.1** **Purpose**

The purpose of the Project Planning process is to produce and coordinate effective and workable plans.

This process determines the scope of the project management and technical activities, identifies process outputs, tasks and deliverables, establishes schedules for task conduct, including achievement criteria, and required resources to accomplish tasks. This is an on-going process that continues throughout a project, with regular revisions to plans.

NOTE The strategies defined in each of the other processes provide inputs and are integrated in the Project Planning process. The Project Assessment and Control process is used to assess whether the plans are integrated, aligned, and feasible.

**6.3.1.2 Outcomes**

As a result of the successful implementation of the Project Planning process:

1. Objectives and plans are defined.
2. Roles, responsibilities, accountabilities, authorities are defined.
3. Resources and services necessary to achieve the objectives are formally requested and committed.
4. Plans for the execution of the project are activated.

**6.3.1.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Project Planning process.

a) **Define the project.** This activity consists of the following tasks:

1. Identify the project objectives and constraints.

NOTE 1 Objectives and constraints include performance and other quality aspects, cost, time and customer satisfaction. Each objective is identified with a level of detail that permits selection, tailoring and implementation of the appropriate processes and activities.

NOTE 2 ISO/IEC 15026*, Systems and software assurance*, and ISO/IEC 27036, *Information security for supplier* *relationships,* provide additional guidance on objectives and constraints related to assurance and security.

1. Define the project scope as established in the agreement.

NOTE This includes all the relevant activities required to satisfy business decision criteria and complete the

project successfully. A project can have responsibility for one or more stages in the complete system life cycle.

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Planning includes defining appropriate actions for maintaining project plans, performing assessments and controlling the project.

1. Define and maintain a life cycle model that is comprised of stages using the defined life cycle models of the organization.

NOTE ISO/IEC TR 24748-1 (IEEE Std 24748-1-2011) provides detailed information regarding life cycle stages and the definition of an appropriate life cycle model. It defines a general set of exemplar life cycle stages, including Concept, Development, Production, Utilization, Support and Retirement.

1. Establish a work breakdown structure based on the evolving system architecture.

NOTE Each element of the system architecture, and appropriate processes and activities are described with a level of detail that is consistent with identified risks. Related tasks in the work breakdown structure are grouped into project tasks. Project tasks identify work items being developed or produced. The PMI Practice Standard for Work Breakdown Structures contains additional details on WBSs.

1. Define and maintain the processes that will be applied on the project.

NOTE These processes are based on the defined processes of the organization (see Life Cycle Model Management process). Annex A contains information on tailoring that can be used to address project specific needs. The definition of the processes include the Entry Criteria; Inputs; Process sequence constraints (predecessor/successor relationships); Process Concurrency Requirements (what processes and tasks are worked concurrently with other process area tasks or activities); Measures of Effectiveness/Measures of Performance attributes; and Scope and Cost parameters (for critically important cost estimation).

b) **Plan project and technical management.** This activity consists of the following tasks:

1. Define and maintain a project schedule based on management and technical objectives and work estimates.

NOTE This includes definition of the duration, relationship, dependencies and sequence of activities, achievement milestones, resources employed and the reviews and schedule reserves for risk management necessary to achieve timely completion of the project.

1. Define achievement criteria for the life cycle stage decision gates, delivery dates and major dependencies on external inputs or outputs.

NOTE The time intervals between internal reviews are defined in accordance with organizational policy on issues such as business and system criticality, schedule and technical risks.

1. Define the costs and plan a budget.

NOTE Costs are based on the schedule, labor estimates, infrastructure costs, procurement items, acquired service and enabling system estimates, and budget reserves for risk management.

1. Define roles, responsibilities, accountabilities, and authorities.

NOTE This includes defining the project organization, staff acquisitions, and the development of staff skills. Authorities include, as appropriate, the legally responsible roles and individuals, e.g., design authorization, safety---

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| authorization, and award of certification or accreditation. | | -`-`,,`,,`,`,,` |
| 5) | Define the infrastructure and services required. |
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| NOTE | This includes defining the capacity needed, its availability and its allocation to project tasks. Infrastructure | |
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includes facilities, tools, communications, and information technology assets. The requirements for enabling systems for each life cycle stage are also specified.

1. Plan the acquisition of materials and enabling system services supplied from outside the project.

NOTE 1 This includes, as necessary, plans for solicitation, supplier selection, acceptance, contract administration and contract closure. The agreement processes are used for the planned acquisitions.

NOTE 2 ISO/IEC 27036, *Information security for supplier relationships*, provides guidance for acquisition of infrastructure and services.

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1. Generate and communicate a plan for project and technical management and execution, including reviews.

NOTE 1 Technical planning for the system is often captured in a Systems Engineering Management Plan (SEMP). ISO/IEC/IEEE 24748-4 provides more detail on the systems engineering technical planning and provides an annotated outline for a SEMP. Software plans for a system are often captured in a Software Development Plan (SDP). Planning for the project is often captured in a Project Management Plan. ISO/IEC/IEEE 16326 provides more detail on project management.

NOTE 2 The strategy activities and tasks from each of the other processes provide inputs and are integrated in the Project Planning process. The Project Assessment and Control process is used to help ensure that the plans are integrated, aligned, and feasible.

c) **Activate the project.** This activity consists of the following tasks

1. Obtain authorization for the project.

NOTE The Portfolio Management process provides the authorization.

1. Submit requests and obtain commitments for necessary resources to perform the project.
2. Implement project plans.

**6.3.2** **Project assessment and control process**

**6.3.2.1** **Purpose**

The purpose of the Project Assessment and Control process is to assess if the plans are aligned and feasible; determine the status of the project, technical and process performance; and direct execution to help ensure that the performance is according to plans and schedules, within projected budgets, to satisfy technical objectives.

This process evaluates, periodically and at major events, the progress and achievements against requirements, plans and overall business objectives. Information is provided for management action when significant variances are detected. This process also includes redirecting the project activities and tasks, as appropriate, to correct identified deviations and variations from other technical management or technical processes. Redirection may include re-planning as appropriate.

**6.3.2.2 Outcomes**

As a result of the successful implementation of the Project Assessment and Control process:

1. Performance measures or assessment results are available.
2. Adequacy of roles, responsibilities, accountabilities, and authorities is assessed.
3. Adequacy of resources is assessed.
4. Technical progress reviews are performed.
5. Deviations in project performance from plans are investigated and analyzed.
6. Affected stakeholders are informed of project status.
7. Corrective action is defined and directed, when project achievement is not meeting targets.
8. Project replanning is initiated, as necessary.
9. Project action to progress (or not) from one scheduled milestone or event to the next is authorized.
10. Project objectives are achieved.

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**6.3.2.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Project Assessment and Control process.

a) **Plan for project assessment and control**. This activity consists of the following task:

1) Define the project assessment and control strategy.

NOTE The strategy identifies the expected Project Assessment and Control activities, including planned assessment methods and timeframes, necessary management and technical reviews.

1. **Assess the project.** This activity consists of the following tasks:
   1. Assess alignment of project objectives and plans with the project context.
   2. Assess management and technical plans against objectives to determine adequacy and feasibility.
   3. Assess project and technical status against appropriate plans to determine actual and projected cost, schedule, and performance variances.
   4. Assess the adequacy of roles, responsibilities, accountabilities, and authorities.

NOTE This includes assessment of the adequacy of personnel competencies to perform project roles and accomplish project tasks. Objective measures are used wherever possible, e.g., efficiency of resource use, project achievement.

1. Assess the adequacy and availability of resources.

NOTE Resources include infrastructure, personnel, funding, time, or other pertinent items. This includes confirming that intra-organizational commitments are satisfied.

1. Assess progress using measured achievement and milestone completion.

NOTE This includes collecting and evaluating data for labor, material, service costs, and technical performance, as well as other technical data about objectives, such as affordability. These are compared against measures of achievement. This includes conducting effectiveness assessments to determine the adequacy of the evolving system against requirements. It also includes the readiness of enabling systems to deliver their services when needed.

1. Conduct required management and technical reviews, audits and inspections.

NOTE These are formal or informal, and are conducted to determine readiness to proceed to the next stage of the life cycle or project milestone, to help ensure that project and technical objectives are being met, or to obtain feedback from stakeholders.

1. Monitor critical processes and new technologies.

NOTE This includes identifying and evaluating technology maturity and insertion.

1. Analyze measurement results and make recommendations.

NOTE Measurement results are analyzed to identify deviations, variations or undesirable trends from planned values that include potential concerns, and to make appropriate recommendations for corrections or preventive actions. This includes, where appropriate, statistical analysis of measures that indicates trends, e.g., fault density to indicate quality of outputs, distribution of measured parameters that indicate process repeatability.

1. Record and provide status and findings from assessment tasks.

NOTE These are generally designated in the agreement, policies and procedures.

1. Monitor process execution within the project.

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NOTE This includes the analysis of process measures and review of trends with respect to project objectives. Any improvement actions identified would be handled through the Quality Assurance process or the Life Cycle Model Management process.

c) **Control the project.** This activity consists of the following tasks:

1. Initiate necessary actions needed to address identified issues.

NOTE 1 This occurs when project or technical achievement is not meeting planned targets. This includes corrective, preventive, and problem resolution actions. Actions generally require replanning or reassignment of personnel, tools and infrastructure assets when inadequacy or unavailability has been detected, or when project or technical achievement exceeds targets or plan. They often impact the cost, schedule, or technical scope or definition. Actions sometimes require changes to the implementation and execution of the life cycle processes.

NOTE 2 Actions are recorded and reviewed to confirm their adequacy and timeliness.

1. Initiate necessary project replanning.

NOTE 1 Project replanning is initiated when project objectives or constraints have changed, or when planning assumptions are shown to be invalid.

NOTE 2 Any change that requires a change to the agreement between acquirer and supplier invokes the Acquisition and Supply Processes.

1. Initiate change actions when there is a contractual change to cost, time or quality due to the impact of an acquirer or supplier request.

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|  | NOTE | | This includes consideration of modified terms and conditions for supply or initiating new supplier selection, |
|  | which invokes the Acquisition and Supply Processes. | | |
| **6.3.3** | -- | **Decision management process** | |
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| 4) | |  | Authorize the project to proceed toward the next milestone or event, if justified. |
|  | NOTE | | The Project Assessment and Control process is used to reach agreement on milestone completion |
|  | `,,`,,`,`,,` | **Purpose** | |
| **6.3.3.1** | |
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The purpose of the Decision Management process is to provide a structured, analytical framework for objectively identifying, characterizing and evaluating a set of alternatives for a decision at any point in the life cycle and select the most beneficial course of action.

NOTE 1 This process is used to resolve technical or project issues and respond to requests for decisions encountered during the system life cycle, in order to identify the alternative(s) that provides the preferred outcomes for the situation. The methods most frequently used for Decision Management are the trade study and engineering analysis. Each of the alternatives is assessed against the decision criteria (e.g., cost impact, schedule impact, programmatic constraints, regulatory implications, technical performance characteristics, critical quality characteristics, and risk). Results of these comparisons are ranked, via a suitable selection model, and are then used to decide on an optimal solution. Key study data, (e.g., assumptions and decision rationale) are typically maintained to inform decision-makers, and support future decision-making.

NOTE 2 When it is necessary to perform a detailed assessment of a parameter for one of the criteria, the System Analysis process is employed to perform the assessment.

**6.3.3.2 Outcomes**

As a result of the successful implementation of the Decision Management process:

1. Decisions requiring alternative analysis are identified.
2. Alternative courses of action are identified and evaluated.
3. A preferred course of action is selected.

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d) The resolution, decision rationale and assumptions are identified.

**6.3.3.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Decision Management process.

a) **Prepare for decisions.** This activity consists of the following tasks:

1. Define a decision management strategy.

NOTE A decision management strategy includes the identification of roles, responsibilities, accountabilities, and authorities. It includes the identification of decision categories and a prioritization scheme. Decisions often arise as a result of an effectiveness assessment, a technical trade-off, a problem needing to be solved, an action needed as a response to risk exceeding the acceptable threshold, or a new opportunity or approval for project progression to the next life cycle stage. Organization or project guidelines determine the degree of rigor and formality to apply to the decision analysis.

1. Identify the circumstances and need for a decision.

NOTE Problems or opportunities and the alternative courses of action that will resolve their outcome are recorded, categorized and reported.

1. Involve relevant stakeholders in the decision-making in order to draw on experience and knowledge.

NOTE It is good practice to identify the subject matter expertise needed for the analysis and the decision.

b) **Analyze the decision information.** This activity consists of the following tasks:

1. Select and declare the decision management strategy for each decision.

NOTE The degree of rigor required to resolve these problems or opportunities is determined, as well as the data and system analysis needed for evaluating the alternatives.

1. Determine desired outcomes and measurable selection criteria.

NOTE The desired value for all quantifiable criteria and the threshold value(s) beyond which the attribute will be unsatisfactory are determined, as well as weighting factors for all criteria.

1. Identify the trade space and alternatives.

NOTE If a large number of alternatives exist, they are qualitatively screened to reduce alternatives to a manageable number for further detailed systems analysis. This screening is often based on qualitative assessments of such factors as risk, cost, schedule, and regulatory impacts.

1. Evaluate each alternative, against the criteria.

NOTE The System Analysis process is used, as necessary, to quantify specific criteria for each trade alternative to be evaluated. This includes new design parameters, different architecture characteristics, and range of values for critical quality characteristics. The System Analysis process assesses the range of parameter variations in order to obtain a sensitivity analysis for each of the trade alternatives evaluated. These results are used to establish the feasibility of the various trade alternatives.

c) **Make and manage decisions.** This activity consists of the following tasks:

1. Determine preferred alternative for each decision.

NOTE Alternatives are evaluated quantitatively, using the selection criteria. The selected alternative generally provides an optimization of, or improvement in, an identified decision.

1. Record the resolution, decision rationale, and assumptions.
2. Record, track, evaluate and report decisions.

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NOTE 1 This includes records of problems and opportunities and their disposition, as stipulated in agreements or organizational procedures and in a manner that permits auditing and learning from experience.

NOTE 2 This allows the organization to confirm that problems have been effectively resolved, that adverse trends have been reversed, and that advantage has been taken of opportunities.

**6.3.4** **Risk management process**

**6.3.4.1** **Purpose**

The purpose of the Risk Management process is to identify, analyze, treat and monitor the risks continually.

The Risk Management process is a continual process for systematically addressing risk throughout the life cycle of a system product or service. It can be applied to risks related to the acquisition, development, maintenance or operation of a system.

NOTE Risk is defined in ISO Guide 73:2009 as "The effect of uncertainty on objectives". This has an attached NOTE 1, "An effect is a deviation from the expected — positive and/or negative." A positive risk is sometimes commonly known as an opportunity, and addressed within the risk management process.

**6.3.4.2 Outcomes**

As a result of the successful implementation of the Risk Management process:

1. Risks are identified.
2. Risks are analyzed.
3. Risk treatment options are identified, prioritized, and selected.
4. Appropriate treatment is implemented.
5. Risks are evaluated to assess changes in status and progress in treatment.

**6.3.4.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Risk Management process.

NOTE ISO/IEC/IEEE 16085 provides a more detailed set of risk management activities and tasks. This risk management process is aligned with ISO 31000:2009 *Risk management — Principles and Guidelines*, and ISO Guide 73:2009,-- *Risk management — Vocabulary.* ISO 9001:2008 standard provides risk-based preventive action requirements in

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a) **Plan risk management.** This activity consists of the following tasks:

1) - Define the risk management strategy.

NOTE `-`,,`,,`,`,,` This includes the risk management process of all supply chain suppliers and describes how risks from all

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suppliers will be raised to the next level(s) for incorporation in the project risk process.

1. Define and record the context of the Risk Management process.

NOTE 1 This includes a description of stakeholders’ perspectives, risk categories, and a description (perhaps by reference) of the technical and managerial objectives, assumptions and constraints. The risk categories include the relevant technical areas of the system and facilitate identification of risks across the life cycle of the system. As noted in ISO 31000 the aim of this step is to generate a comprehensive list of risks based on those events that might create, enhance, prevent, degrade, accelerate or delay the achievement of objectives.

NOTE 2 Opportunities, which are one type of risk, provide potential benefits for the system or project. Each of the opportunities pursued have associated risks that detract from the expected benefit. This includes the risks associated with not pursuing an opportunity, as well as the risk of not achieving the effects of the opportunity.

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1. **Manage the risk profile.** This activity consists of the following tasks:
   1. Define and record the risk thresholds and conditions under which a level of risk may be accepted.
   2. Establish and maintain a risk profile.

NOTE The risk profile records: the risk management context; a record of each risk’s state including its likelihood of occurrence, consequences, and risk thresholds; the priority of each risk based on risk criteria supplied by the stakeholders; and the risk action requests along with the status of their treatment. The risk profile is updated when there are changes in an individual risk’s state. The priority in the risk profile is used to determine the application of resources for treatment.

* 1. Periodically provide the relevant risk profile to stakeholders based upon their needs.

1. **Analyze risks.** This activity consists of the following tasks:
   1. Identify risks in the categories described in the risk management context.

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NOTE Risks are commonly identified through various analyses, such as safety, reliability, producibility, and performance analyses; technology, architecture, and readiness assessments; and trade studies. These risks may be identified early in the life cycle and continue into the utilization, support, and retirement of the system. Additionally, risks are often identified through the analysis of the measures of the system.

1. Estimate the likelihood of occurrence and consequences of each identified risk.
2. Evaluate each risk against its risk thresholds.
3. For each risk that does not meet its risk threshold, define and record recommended treatment strategies and measures.

NOTE Risk treatment strategies include, but are not limited to, eliminating the risk, reducing its likelihood of occurrence or severity of consequence, or accepting the risk. Treatments also include taking or increasing risk in order to pursue an opportunity. Measures provide information about the effectiveness of the treatment alternatives.

1. **Treat risks.** This activity consists of the following tasks:
   1. Identify recommended alternatives for risk treatment.
   2. Implement risk treatment alternatives for which the stakeholders determine that actions should be taken to make a risk acceptable.
   3. When the stakeholders accept a risk that does not meet its threshold, consider it a high priority and monitor it continually to determine if any future risk treatment actions are necessary.
   4. Once a risk treatment is selected, coordinate management action.

NOTE Refer to Project Assessment and Control process.

1. **Monitor risks.** This activity consists of the following tasks:
   1. Continually monitor all risks and the risk management context for changes and evaluate the risks when their state has changed.
   2. Implement and monitor measures to evaluate the effectiveness of risk treatments.
   3. Continually monitor for the emergence of new risks and sources throughout the life cycle.

**6.3.5** **Configuration management process**

**6.3.5.1** **Purpose**

The purpose of Configuration Management (CM) is to manage and control system elements and configurations over the life cycle. CM also manages consistency between a product and its associated configuration definition.

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**6.3.5.2 Outcomes**

As a result of the successful implementation of the Configuration Management process:

1. Items requiring configuration management are identified and managed.
2. Configuration baselines are established.
3. Changes to items under configuration management are controlled.
4. Configuration status information is available.
5. Required configuration audits are completed.
6. System releases and deliveries are controlled and approved.

**6.3.5.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Configuration Management process.

a) **Plan configuration management.** This activity consists of the following tasks:

1. Define a configuration management strategy.

NOTE 1 This includes details covering:

1. Roles, responsibilities, accountabilities, and authorities.
2. Disposition of, access to, release of and control of changes to configuration items.
3. The necessary baselines to be established.
4. The locations and conditions of storage, the storage media and their environment, in accordance with designated levels of integrity, security and safety.
5. The criteria or events for commencing configuration control and maintaining baselines of evolving configurations.
6. The audit strategy and the responsibilities for assessing continual integrity and security of the configuration definition information.
7. Change management, including any planned configuration control boards, regular and emergency change requests; and procedures for change management.

NOTE 2 The configuration management strategy needs to identify how configuration management will be coordinated across the set of acquirer, supplier, and supply chain organizations. The strategy covers the life of the system, or the extent of the contract, as appropriate.

NOTE 3 Additional guidance regarding configuration management activities can be found in ISO 10007, IEEE Std 828, and ANSI EIA-649-B. Also, domain specific practices, such as SAE ARP4754A, *Guidelines for Development of* *Civil*-- *Aircraft and Systems*, provide additional application detail for the domain.

2) `,,`,,,`,``,,,`,`,``,``,,,,,,` Define the archive and retrieval approach for configuration items, configuration management

artifacts and data.

NOTE - This includes data retention procedures.

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b) **Perform** `,,`,,`,`,,` **configuration identification.** This activity consists of the following tasks:

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1. Identify the system elements and information items that are configuration items.

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NOTE Configuration items receive special attention. They are usually assigned unique identifiers and are often the subject of reviews and configuration audits. Items subject to configuration control usually include requirements, product and system elements, information items, and baselines.

1. Identify the hierarchy and structure of system information.

NOTE This includes product or system element hierarchy, system decomposition, etc.

1. Establish system, system element, and information item identifiers.

NOTE Items are distinguished by unique, durable identifiers or markings, where appropriate. The identifiers are in accordance with relevant standards and product sector conventions, such that the items under configuration control are unambiguously traceable to their specifications or equivalent, recorded descriptions.

1. Define baselines through the life cycle.

NOTE Baselines capture the evolving configuration states of system elements at designated times or under defined circumstances. The content for the baselines is developed through the technical processes, but is formalized at a point in time through the CM process. Baselines form the basis for the next change. Selected baselines typically become formalized between acquirer and supplier, depending on the practices of the industry and the contractual involvement of the acquirer in the configuration management process. There are generally three major types of baselines at the system level; functional baseline, allocated baseline, and product baseline. These vary by domain or local strategy.

1. Obtain acquirer and supplier agreement to establish a baseline.

NOTE The Project Assessment & Control process is used to reach agreement.

c) **Perform configuration change management.** This activity consists of the following tasks:

NOTE Configuration change management establishes procedures and methods for managing change to a baseline once it is established. This is sometimes referred to as configuration control.

1. Identify and record Requests for Change and Requests for Variance.

NOTE A request for variance is sometimes referred to as a deviation, waiver, or concession.

1. Coordinate, evaluate, and disposition Requests for Change and Requests for Variance.

NOTE This includes an impact assessment of proposed changes, including impact on project plans, costs, benefits, risks, quality, and schedule. A decision is made on whether to implement or close the change request.

1. Submit requests for review and approval.

NOTE Requests for Change and Requests for Variance are often under the formal control of a Configuration Control Board (CCB). Evaluation includes analysis of need versus impact.

1. Track and manage approved changes to the baseline, Requests for Change, and Requests for Variance.

NOTE 1 This task involves prioritization, tracking, scheduling, and closing changes. Changes are then made through the Technical Processes. These changes are verified or validated through the Verification and Validation Processes, to help ensure that the approved changes have been made.

NOTE 2 Any changes and rationales are generally recorded.

d) **Perform configuration status accounting.** This activity consists of the following tasks:

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| --- | --- | --- | --- |
| -- | 1) | Develop and maintain the configuration management status information, for system elements, | |
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| decisions regarding system elements throughout the product life cycle. This includes taking into account the nature | | |
|  | baselines, and releases. | |  |
|  | NOTE 1 | Configuration status accounting provides the data on the status of controlled products needed to make | |
| -` | of the items under configuration control. Configuration descriptions conform, where possible, to product or technology | | |
| ---`,,`,,`,`,,` | rationale for the baselines and releases and associated authorizations in configuration data are generally recorded. | | |
|  | standards. Configuration information permits forward and backward traceability to other configuration states. The | | |
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Configuration records are maintained through the system life cycle and then archived according to agreements, relevant legislation or best industry practice.

NOTE 2 The recording, retrieval and consolidation of the current configuration status and the status of all preceding configurations to confirm information correctness, timeliness, integrity and security is managed. Audits are performed to verify conformance of a baseline to drawings, interface control documents and other agreement requirements.

* 1. Capture, store and report configuration management data.

1. **Perform configuration evaluation.** This activity consists of the following tasks:
   1. Identify the need for CM audits and schedule the events.
   2. Verify the product configuration meets the configuration requirements.

NOTE This is performed by comparing requirements, constraints, and waivers (variances) with results of formal verification activities.

1. Monitor the incorporation of approved configuration changes.
2. Assess whether the system meets baseline functional and performance capabilities.

NOTE This is sometimes called a functional configuration audit (FCA).

1. Assess whether the system conforms to the operational and configuration information items.

NOTE This is sometimes called a physical configuration audit (PCA).

* 1. Record the CM audit results and disposition action items.

1. **Perform release control.** This activity consists of the following tasks:
   1. Approve system releases and deliveries.

NOTE 1 The purpose of a release is to authorize the use of a system for a specific purpose, with or without restrictions. Examples are releases for tests or for operational use.

NOTE 2 Releases generally include a set of changes. These changes are made through the Technical Processes, and-- then verified or validated through the Verification and Validation Processes. Approval of a release generally includes acceptance of the verified and validated changes.

2) `,,`,,,`,``,,,`,`,``,``,,,,,,` Track and manage system releases and deliveries.

NOTE - Where appropriate, master copies of all system elements are generally maintained for the life of the system.

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The`,,`,,`,`,,` system elements are handled, stored, packaged, and delivered in accordance with the policies of the organizations involved.

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**6.3.6** **Information management process**

**6.3.6.1** **Purpose**

The purpose of the Information Management process is to generate, obtain, confirm, transform, retain, retrieve, disseminate and dispose of information, to designated stakeholders.

Information management plans, executes, and controls the provision of information to designated stakeholders that is unambiguous, complete, verifiable, consistent, modifiable, traceable, and presentable. Information includes technical, project, organizational, agreement, and user information. Information is often derived from data records of the organization, system, process, or project.

**6.3.6.2 Outcomes**

As a result of the successful implementation of the Information Management process:

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1. Information to be managed is identified.
2. Information representations are defined.
3. Information is obtained, developed, transformed, stored, validated, presented, and disposed of.
4. The status of information is identified.
5. Information is available to designated stakeholders.

**6.3.6.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Information Management process.

NOTE ISO/IEC/IEEE 15289 summarizes requirements for the content of life cycle process information items (documentation) and provides guidance on their development.

a) **Prepare for information management.** This activity consists of the following tasks:

1. Define the strategy for information management.

NOTE Information about the same topic can be developed in different ways at different points in the life cycle and for different audiences.

1. Define the items of information that will be managed.

NOTE This includes the information that will be managed during the system life cycle and possibly maintained for a defined period beyond. This is done according to organizational policy, agreements, or legislation.

1. Designate authorities and responsibilities for information management.

NOTE Due regard is paid to information and data legislation, security and privacy, e.g., ownership, agreement restrictions, rights of access, intellectual property and patents. Where restrictions or constraints apply, information is identified accordingly. Staff having knowledge of such items of information are informed of their obligations and responsibilities.

1. Define the content, formats and structure of information items.

NOTE The information originates and terminates in many forms (e.g., audiovisual, textual, graphical, numerical) and mediums (e.g., electronic, printed, magnetic, optical). Organization constraints, e.g., infrastructure, inter-organizational communications, and distributed project workings, are taken into account. Relevant information item standards and conventions are used according to policy, agreements and legislation constraints.

1. Define information maintenance actions.

NOTE Information maintenance includes status reviews of stored information for integrity, validity and availability. It also includes any needs for replication or transformation to an alternative medium, as necessary, either to retain infrastructure as technology changes so that archived media can be read or to migrate archived media to newer technology.

b) **Perform information management.** This activity consists of the following tasks:

1. Obtain, develop, or transform the identified items of information.

NOTE This includes collecting the data, information, or information items from appropriate sources (e.g., resulting from any life cycle process), and writing, illustrating, or transforming it into useable information for stakeholders. It includes reviewing, validating, and editing information per information standards.

1. Maintain information items and their storage records, and record the status of information.

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|  | NOTE 1 Information items are maintained according to their integrity, security and privacy requirements. The status | |
| -- | of information items is maintained, (e.g., version description, date of issue or validity date, record of distribution, | |
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NOTE 2 The source data and tools used to transform information, along with the resulting documentation is placed under configuration control in accordance with the Configuration Management process. ISO/IEC/IEEE 26531 provides requirements for content management systems useful for life cycle information and documentation.

1. Publish, distribute or provide access to information and information items to designated stakeholders.

NOTE Information is provided to designated stakeholders in an appropriate form, as required by agreed schedules or defined circumstances. Information items include official documentation used for certification, accreditation, license or assessment ratings, as required.

1. Archive designated information.

NOTE Archiving is done in accordance with the audit, knowledge retention, and project closure purposes. The media, location and protection of the information are selected in accordance with the specified storage and retrieval periods, and with organization policy, agreements and legislation. Arrangements are put in place to retain necessary information items after project closure.

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| 5) | |  | Dispose of unwanted, invalid or unvalidated information. |
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| **6.3.7** | -`,,`,,,`,``,,,`,`,``,``,,,,,,` | **Measurement process** | |
| NOTE | | | This is done according to organization policy, and security and privacy requirements. |
|  | -` |  |  |
|  | ---`,,`,,`,`,,` |  | **Purpose** |
| **6.3.7.1** | |  |

The purpose of the Measurement process is to collect, analyze, and report objective data and information to support effective management and demonstrate the quality of the products, services, and processes.

**6.3.7.2 Outcomes**

As a result of the successful implementation of the Measurement process:

1. Information needs are identified.
2. An appropriate set of measures, based on the information needs are identified or developed.
3. Required data is collected, verified, and stored.
4. The data is analyzed and the results interpreted.
5. Information items provide objective information that support decisions.

**6.3.7.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the measurement process.

NOTE 1 ISO/IEC 15939 (IEEE Std 15939-2007) provides a more detailed set of measurement activities and tasks that are aligned with the activities and tasks shown below.

NOTE 2 Clause 8 of ISO 9001:2008 specifies Quality Management System requirements for measurement and monitoring of processes and products.

1. **Prepare for measurement.** This activity consists of the following tasks:
   1. Define the measurement strategy.
   2. Describe the characteristics of the organization that are relevant to measurement.
   3. Identify and prioritize the information needs.

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NOTE The information needs are based on the organization's business objectives, the project objectives, identified risks, and other items related to project decisions.

* 1. Select and specify measures that satisfy the information needs.
  2. Define data collection, analysis, access, and reporting procedures.
  3. Define criteria for evaluating the information items and the Measurement process.
  4. Identify and plan for the necessary enabling systems or services to be used.

1. **Perform measurement.** This activity consists of the following tasks:
   1. Integrate procedures for data generation, collection, analysis and reporting into the relevant processes.

NOTE Some of these required changes are integrated into other life cycle processes.

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1. Collect, store, and verify data.
2. Analyze data and develop information items.
3. Record results and inform the measurement users.

NOTE The measurement analyses results are reported to relevant stakeholders in a timely, usable fashion to support decision making and assist in corrective actions, risk management, and improvements. Results are reported to decision process participants, technical and management review participants, and product and process improvement process owners.

**6.3.8** **Quality assurance process**

**6.3.8.1** **Purpose**

The purpose of the Quality Assurance process is to help ensure the effective application of the organization’s Quality Management process to the project.

Quality Assurance focuses on providing confidence that quality requirements will be fulfilled. Proactive analysis of the project life cycle processes and outputs is performed to assure that the product being produced will be of the desired quality and that organization and project policies and procedures are followed.

**6.3.8.2 Outcomes**

As a result of the successful implementation of the Quality Assurance process:

1. Project quality assurance procedures are defined and implemented.
2. Criteria and methods for quality assurance evaluations are defined.
3. Evaluations of the project’s products, services, and processes are performed, consistent with quality management policies, procedures, and requirements.
4. Results of evaluations are provided to relevant stakeholders.
5. Incidents are resolved.
6. Prioritized problems are treated.

NOTE Outcomes a through d align with the outcomes of the Quality Management process and subclause 4.1, General Requirements, of ISO 9001:2008.

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**6.3.8.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures.

a) **Prepare for quality assurance.** This activity consists of the following tasks**:**

1. Define a Quality Assurance strategy

NOTE 1 The strategy is consistent with the Quality Management policies, objectives, and procedures, and includes:

1. Project quality assurance procedures
2. Defined roles, responsibilities, accountabilities, and authorities.
3. Activities appropriate to each life cycle process.
4. Activities appropriate to each supplier (including subcontractors).
5. Required verification, validation, monitoring, measurement, inspection, and test activities specific to the product or service.
6. Criteria for product or service acceptance and evaluation criteria and methods for process, product, and service evaluations.

NOTE 2 The strategy is consistent with the organizational Quality Management process to help ensure that organizational quality management policies and procedures are satisfied.

1. Establish independence of quality assurance from other life cycle processes.

NOTE Resources for quality assurance are often assigned from distinct organizations for independence from project management.

1. **Perform product or service evaluations**.
2. Evaluate products and services for conformance to established criteria, contracts, standards, and regulations.

NOTE This includes system quality requirements that are derived from the Stakeholder Needs and Requirements Definition Process and System Requirements Definition Process. See ISO/IEC 25010 for more information.

* 1. Perform verification and validation of the outputs of the life cycle processes to determine conformance to specified requirements.

1. **Perform process evaluations.** This activity consists of the following tasks:
   1. Evaluate project life cycle processes for conformance.
   2. Evaluate tools and environments that support or automate the process for conformance.
   3. Evaluate supplier processes for conformance to process requirements.

NOTE Consider items such as a collaborative development environment, process measures that suppliers are required to provide, or a risk process that suppliers are required to use.

1. **Manage quality assurance records and reports.** This activity consists of the following tasks:
2. Create records and reports related to quality assurance activities.

NOTE Create records and reports in accordance with organizational, regulatory, and project requirements, using the information management process.

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1. Maintain, store, and distribute records and reports.
2. Identify incidents and problems associated with product, service, and process evaluations.

NOTE This includes the capture of lessons learned and the conduct of surveillance reviews of process implementation through the supply chain.

e) **Treat incidents and problems.** This activity consists of the following tasks:

NOTE 1 In the terminology of quality management, problems are often described as “non-conformities” which, if left untreated, could cause the project to fail to meet its requirements.

NOTE 2 For additional information and examples of problem categories and priority classifications, see ISO/IEC TR 24748-1 (IEEE Std 24748-1-2011), Annex C.

1. Incidents are recorded, analyzed and classified.
2. Incidents are resolved or elevated to problems.
3. Problems are recorded, analyzed and classified.

NOTE Analysis results include potential treatment options.

1. Treatments for problems are prioritized and implementation is tracked.

NOTE

Process.

Implementation is done in the Technical Processes after initiation by the Project Assessment and Control

1. Trends in incidents and problems are noted and analyzed.
2. Stakeholders are informed of the status of incidents and problems.
3. Incidents and problems are tracked to closure.

**6.4 Technical processes**

The Technical Processes are used to define the requirements for a system, to transform the requirements into an effective product, to permit consistent reproduction of the product where necessary, to use the product to provide the required services, to sustain the provision of those services and to dispose of the product when it is retired from service.

The Technical Processes define the activities that enable organization and project functions to optimize the benefits and reduce the risks that arise from technical decisions and actions. These activities enable products and services to possess the timeliness and availability, the cost effectiveness, and the functionality, reliability, maintainability, producibility, usability and other qualities required by acquiring and supplying organizations. They also enable products and services to conform to the expectations or legislated requirements of society, including health, safety, security and environmental factors.

The Technical Processes consist of the following:

1. Business or Mission Analysis process;
2. Stakeholder Needs and Requirements Definition process;
3. System Requirements Definition process;
4. Architecture Definition process;
5. Design Definition process;
6. System Analysis process;
7. Implementation process;

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1. Integration process;
2. Verification process;
3. Transition process;
4. Validation process;
5. Operation process;
6. Maintenance process;
7. Disposal process.

NOTE 1 For software and hardware system elements, these processes are applied at recursively lower levels for system definition and recursively higher levels for system realization for stakeholder needs and requirements definition, system requirements definition, architecture definition, design definition, system analysis, integration, verification and validation.

NOTE 2 These processes are often performed concurrently, iterating between one another to establish a solution that is balanced with respect to requirements, critical performance measures, and critical quality characteristics. At any level of abstraction, system requirements and models are made consistent via iterations of applicable technical processes. When requirements and models are not directly capable of being implemented, the same processes are repeated recursively at a more detailed level, e.g., the next lower level of the system hierarchy.

NOTE 3 The concept of life cycle stages and the application of these processes in any stage are described in detail in ISO/IEC TR 24748-1 (IEEE Std 24748-1- 2011). It has a complete set of example stages and stage outcomes for the enactment of technical processes within a system life cycle.

NOTE 4 Interface Management is a set of activities that cut across the systems engineering processes. These are cross-cutting activities of the Technical and Technical Management processes that apply and track as a specific view of the processes and system. See Annex E of this standard for an example Interface Management Process View and the INCOSE *Systems Engineering Handbook*, Version 4, section 9.6 for more information.

**6.4.1** **Business or mission analysis process**

**6.4.1.1** **Purpose**

The purpose of the Business or Mission Analysis process is to define the business or mission problem or opportunity, characterize the solution space, and determine potential solution class(es) that could address a problem or take advantage of an opportunity.

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| NOTE 1 | Business and Mission Analysis is related to the organization encompassing all stakeholders concerned by the | |
| -- |  | relates to the leadership's intended way of operating the organization. It describes the organization’s |
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activities of the system life cycle. This process interacts with the organization's strategy, which is generally outside the scope of 15288. The results of the organization's strategic analysis include the organizational Concept of Operations, strategic goals and plans, new market or mission elements, and identified problems and opportunities. The organization's strategy establishes the context within which the business or mission analysis is performed. The organizational Concept

assumptions `,,`,,`,`,,` and how it intends to use the system to be developed, existing systems, and possible future systems in

support of an overall operation or series of operations of the business. In the case that the organization is the system-of-interest,--- the organization’s strategy is part of the system definition.

NOTE 2 This process has application through the life of the system solution and is revisited if there are changes in the environment, needs, or other drivers.

NOTE 3 In some domains, this relates to the concept of identifying and analyzing capabilities that are needed or desired by the organization. This process focuses on the necessary capabilities and interacts with the Portfolio Management process for identifying the trade space that can address the capability. The identified problems or opportunities are often translated into target capabilities. As applicable within a given domain, the problem or opportunity space includes the target capabilities.

**6.4.1.2 Outcomes**

As a result of the successful implementation of the Business or Mission Analysis process:

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1. The problem or opportunity space is defined.
2. The solution space is characterized.
3. Preliminary operational concepts and other concepts in the life cycle stages are defined.
4. Candidate alternative solution classes are identified and analyzed.
5. The preferred candidate alternative solution class(es) are selected.
6. Any enabling systems or services needed for business or mission analysis are available.
7. Traceability of business or mission problems and opportunities and the preferred alternative solution classes is established.

**6.4.1.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Business or Mission Analysis process.

a) **Prepare for business or mission analysis.** This activity consists of the following tasks:

1. Review identified problems and opportunities in the organization strategy with respect to desired organization goals or objectives.

NOTE This includes problems or opportunities with respect to the organization business or mission, vision, Concept of Operations, and other organization strategic goals and objectives. This includes identified deficiencies or gaps in existing capabilities, systems, products, or services.

1. Define the business or mission analysis strategy.

NOTE This includes the approach to be used to identify and define the problem space, characterize the solution space and select a solution class.

1. Identify and plan for the necessary enabling systems or services needed to support business or mission analysis.

NOTE This includes identification of requirements and interfaces for enabling systems. Enabling systems for business or mission analysis include the business systems and repositories of the organization.

1. Obtain or acquire access to the enabling systems or services to be used.

NOTE The Validation process is used to objectively confirm that the enabling system achieves its intended use for its enabling functions.

b) **Define the problem or opportunity space.** This activity consists of the following tasks:

1. Analyze the problems and opportunities in the context of relevant trade-space factors.

NOTE 1 This analysis is focused on understanding the scope, basis, or drivers of the problems or opportunities, as opposed to the synthesis that is the focus of system analysis and decision management needed for trade studies. The focus here includes changes in mission requirements, business opportunities, capabilities, performance improvement, or lack of existing systems, security and safety improvement, factors such as cost and effectiveness, regulation changes, user dissatisfaction, and PESTEL factors (Political, Economic, Social, Technological, Environmental, and Legal). This may be accomplished through external, internal, or SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis.

NOTE 2 The outputs of the analysis are considered as part of the portfolio management decisions.

1. Define the mission, business, or operational problem or opportunity.

NOTE This definition includes the context and any key parameters, without regard to a specific solution, since the solution could be an operational change, a change to an existing product or service, or a new system.

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c) **Characterize the solution space.** This activity consists of the following tasks:

1. Define preliminary operational concepts and other concepts in life cycle stages.

NOTE 1 This involves the identification of major stakeholder groups such as customers, users, administrations, regulators, and system owners. that are defined in the Stakeholder Needs and Requirements Definition process.

NOTE 2 Preliminary life cycle concepts include preliminary acquisition concepts, preliminary deployment concepts, preliminary operational concepts, preliminary support concepts, and preliminary retirement concepts. Operational concepts include high level operational modes or states, operational scenarios, potential use cases, or usage within a proposed business strategy. These concepts enable feasibility analysis and evaluation of alternatives. These concepts are further refined within the Stakeholder Needs and Requirements Definition process.

NOTE 3 The operating environment may be known to have vulnerabilities associated with specific security threats and safety hazards. These vulnerabilities need to be understood in association with the product under development. The system and human interfaces are an element of the system assurance context and related vulnerabilities are examined in the context of mission critical threads.

1. Identify candidate alternative solution classes that span the potential solution space.

NOTE These may range from simple operational changes to various system developments or modifications. The solution space can include the identification of existing systems, products, and services that can address the need for operational or functional modifications. This includes deducing what potential expected services will be needed. The solution space characterization often invokes the Architecture Definition process for a user architecture viewpoint resulting in architecture views (e.g., capability views, program views and operational views) as proposed by ISO/IEC 42010.

1. **Evaluate alternative solution classes.** This activity consists of the following tasks:
   1. Assess each alternative solution class.

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NOTE 1 Each alternative solution class is assessed against defined criteria that are established based on the organization's strategy. Feasibility of the solution class is one key decision criteria. The Portfolio Management process provides some criteria to be considered.

NOTE 2 The System Analysis process is used to assess the value of each criterion for each alternative solution class. Structured affordability trade-offs are recommended. Including cost as a criterion will aid affordability decisions. The assessment of alternatives can include modeling, simulation, analytical techniques, or expert judgment to understand the risks, feasibility and value of the alternative candidate solution classes.

1. Select the preferred alternative solution class(es).

NOTE The Decision Management process is used to evaluate alternatives and to guide selection. Selected alternatives are validated in the context of the organization's strategy. Feedback on risks, feasibility, market factors, and alternatives is provided for use in updating the organization's strategy.

e) **Manage the business or mission analysis**. This activity consists of the following tasks:

1. Maintain traceability of business or mission analysis.

NOTE Through the life cycle, bi-directional traceability is maintained between the business and mission problems and opportunities and the preferred alternative solution classes with the organizational strategy, stakeholder needs and requirements, and system analysis results supporting decisions.

1. Provide key information items that have been selected for baselines.

NOTE The Configuration Management process is used to establish and maintain configuration items and baselines. This process (Business or Mission Analysis) identifies candidates for the baseline, and then provides the information items to CM.

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**6.4.2** **Stakeholder needs and requirements definition process**

**6.4.2.1** **Purpose**

The purpose of the Stakeholder Needs and Requirements Definition process is to define the stakeholder requirements for a system that can provide the capabilities needed by users and other stakeholders in a defined environment.

It identifies stakeholders, or stakeholder classes, involved with the system throughout its life cycle, and their needs. It analyzes and transforms these needs into a common set of stakeholder requirements that express the intended interaction the system will have with its operational environment and that are the reference against which each resulting operational capability is validated. The stakeholder requirements are defined considering the context of the system-of-interest with the interoperating systems and enabling systems.

**6.4.2.2 Outcomes**

As a result of the successful implementation of the Stakeholder Needs and Requirements Definition process:

1. Stakeholders of the system are identified.
2. Required characteristics and context of use of capabilities and concepts in the life cycle stages, including operational concepts, are defined.
3. Constraints on a system are identified.
4. Stakeholder needs are defined.
5. Stakeholder needs are prioritized and transformed into clearly defined stakeholder requirements.
6. Critical performance measures are defined.
7. Stakeholder agreement that their needs and expectations are reflected adequately in the requirements is achieved.
8. Any enabling systems or services needed for stakeholder needs and requirements are available.
9. Traceability of stakeholder requirements to stakeholders and their needs is established.

**6.4.2.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Stakeholder Needs and Requirements Definition process.

1. **Prepare for stakeholder needs and requirements definition.** This activity consists of the followingtasks:
2. Identify the stakeholders who have an interest in the system throughout its life cycle.

NOTE This includes individuals and classes of stakeholders who are users, operators, supporters, developers, producers, trainers, maintainers, disposers, acquirer and supplier organizations, parties responsible for external interfacing entities, regulatory bodies and others who have a legitimate interest in the system. Where direct communication is not practicable (e.g., for consumer products and services), representatives or designated proxy stakeholders are selected.

1. Define the stakeholder needs and requirements definition strategy.

NOTE Some stakeholders have interests that oppose the system or oppose each other. When the stakeholder interests oppose each other, but do not oppose the system, this process is intended to gain consensus among the stakeholder classes to establish a common set of acceptable requirements. The intent or desires of those that oppose the system, or detractors of the system, are addressed through the Risk Management process, threat analyses of the System Analysis process, or the system requirements for security, adaptability, or resilience. In this case, the stakeholder needs are not satisfied, but rather addressed in a manner to help ensure system assurance and integrity if actions from the detractors are encountered.

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1. Identify and plan for the necessary enabling systems or services needed to support stakeholder needs and requirements definition.

NOTE This includes identification of requirements and interfaces for the enabling systems. Enabling systems for stakeholder needs and requirements definition include tools for facilitation and requirements management.

1. Obtain or acquire access to the enabling systems or services to be used.

NOTE The Validation process is used to objectively confirm that the enabling system achieves its intended use for its enabling functions.

b) **Define stakeholder needs.** This activity consists of the following tasks:

1. Define context of use within the concept of operations and the preliminary life cycle concepts.

NOTE Context of use is often captured using a Context of Use Description [ISO/IEC 25063.3]. Preliminary life cycle concepts are developed by the Business or Mission Analysis process.

1. Identify stakeholder needs.

NOTE 1 Identification of stakeholder needs includes elicitation of needs directly from the stakeholder, identification of implicit stakeholder needs based on domain knowledge and context understanding, and documented gaps from previous activities. Needs often include measures of effectiveness. Functional analysis is often used to aid the elicitation of needs. Also quality characteristics of the quality model in ISO/IEC 25010 and quality model application to requirements analysis in ISO/IEC 25030 are useful to elicit and identify quality requirements of non-functional requirements, which are often implicit stakeholder needs.

NOTE 2 Stakeholder needs describe the needs, wants, desires, expectations and perceived constraints of identified stakeholders. Understanding stakeholder needs for the minimum security and privacy requirements necessary for the operational environment minimizes the potential for disruption in plans, schedules, and performance. If significant issues are likely to arise relating to users and other stakeholders and their involvement in or interaction with a system, recommendations for identifying and treating human-system issues can be found in ISO TS 18152.

1. Prioritize and down-select needs.

NOTE The Decision Management process is typically used to support prioritization. The System Analysis process is used to analyze needs for feasibility or other factors.

1. Define the stakeholder needs and rationale.

NOTE Needs concentrate on system purpose and behavior, and are described in the context of the operational environment and conditions. It is useful to trace needs to their sources and rationale.

1. **Develop the operational concept and other life cycle concepts.** This activity consists of the followingtasks:

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| NOTE | Other life cycle concepts can include acquisition concepts, deployment concepts, support concepts, | |
| security concepts, and retirement concepts. | | In this activity, the preliminary life cycle concepts defined within the |
| Business | or Mission Analysis process are | further developed in the context of specific stakeholder needs, as |

associated scenarios and interactions are defined. See ISO/IEC/IEEE 29148 clauses 5 and 6 for more information on operational concepts, and ISO/IEC/IEEE 29148 Annex A for an annotated outline for a System Operational Concept.

1. Define a representative set of scenarios to identify all required capabilities that correspond to anticipated operational and other life cycle concepts.

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|  | NOTE 1 Scenarios are used to analyze the operation of the system in its intended environment in order to identify | |
|  | additional needs or requirements that possibly have not been explicitly identified by any of the stakeholders, e.g., legal, | |
|  | regulatory and social obligations. The context of use of the system is identified and analyzed, including the activities | |
|  | that users perform to achieve system objectives, the relevant characteristics of the end users of the system (e.g., | |
|  | expected training, degree of fatigue), the physical environment (e.g., available light, temperature) and any equipment | |
|  | to be used (e.g., protective or communication equipment). The social and organizational influences on users that | |
|  | could affect system use or constrain its design are analyzed when applicable. Scenarios centered on attackers, their | |
|  | environments, tools, techniques, and capabilities are key considerations for operational concept development. | |
|  | Scenarios are prioritized in order to reflect the weighted importance of the various operational needs. | |
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NOTE 2 These scenarios often motivate updates to the operational or other life cycle concepts. Abuse and failure scenarios highlight the need for additional functional requirements (or more specific derived requirements) to mitigate risks that are identified in the abuse or failure scenarios.

1. Identify the interaction between users and the system.

NOTE 1 Usability requirements take into account human capabilities and skills limitations. Where possible, applicable standards, e.g., ISO 9241, and accepted professional practices are used in order to define:

1. Physical, mental, and learned capabilities.
2. Work place, environment and facilities, including other equipment in the context of use.
3. Normal, unusual, and emergency conditions.
4. Operator and user recruitment, training and culture.

NOTE 2 If usability is important, usability requirements are planned, specified, and implemented through the life cycle processes. Refer to ISO TS 18152 for information on human-system issues and ISO/IEC 25060:2010 for information on usability.

1. **Transform stakeholder needs into stakeholder requirements.** This activity consists of the followingtasks:

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1. Identify the constraints on a system solution.

NOTE These result from 1) instances or areas of stakeholder-defined solution; 2) implementation decisions made at higher levels of system hierarchical structure; 3) required use of defined enabling, legacy, or interfacing systems or system elements, resources and staff; or 4) stakeholder defined affordability objectives. Include those that are unavoidable consequences of existing agreements, management decisions and technical decisions.

1. Identify the stakeholder requirements and functions that relate to critical quality characteristics, such as assurance, safety, security, environment, or health.

NOTE 1 See ISO/IEC/IEEE 15026 for additional information on system and software assurance.

NOTE 2 Identifying safety risks facilitates the identification of safety requirements and functions. Safety risks include those associated with methods of operations and support, health and safety, threats to property and environmental influences. Use applicable standards, e.g., IEC 61508, and accepted professional practices.

NOTE 3 Identifying security risks facilitates the identification of additional security requirements and functions. If warranted, include applicable areas of system security, including physical, procedural, communications, computers, programs, data and emissions. This includes access and damage to protected personnel, properties and information, compromise of sensitive information, and denial of approved access to property and information. This also includes the required security functions, such as mitigation and containment, referencing applicable standards and accepted professional practices where mandatory or relevant.

NOTE 4 See ISO/IEC 25030 for further information regarding quality characteristics from a quality in use perspective.

1. Define stakeholder requirements, consistent with life cycle concepts, scenarios, interactions, constraints, and critical quality characteristics.

NOTE 1 See ISO/IEC/IEEE 29148 clauses 5 and 6 for more information on stakeholder requirements, and clauses 8 and 9 for a description of and an annotated outline for a Stakeholder Requirements Specification.

NOTE 2 The stakeholder requirements are reviewed at key decision times in the life cycle to help ensure that account is taken of any changes of need.

NOTE 3 The stakeholder requirements are recorded in a form suitable for requirements management through the life cycle. These records establish the stakeholder requirements baseline, and retain changes of need and their origin throughout the system life cycle. These records are the basis for traceability to decisions made by the Business or Mission Analysis process as well as stakeholder needs, system requirements, and subsequent system elements.

NOTE 4 The stakeholder requirements are the basis of the validation criteria for the system and system elements.

e) **Analyze stakeholder requirements.** This activity consists of the following tasks:

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1. Analyze the complete set of stakeholder requirements.

NOTE 1 Stakeholder requirements are analyzed for characteristics of individual requirements, as well as characteristics of the set of requirements. Potential analysis characteristics include that the requirements are necessary, implementation free, unambiguous, consistent, complete, singular, feasible, traceable, verifiable, affordable, and bounded. ISO/IEC/IEEE 29148 provides additional information on characteristics of requirements.

NOTE 2 The System Analysis process is used to assess feasibility and affordability. The Verification and Validation processes are used in the review of stakeholder requirements.

1. Define critical performance measures that enable the assessment of technical achievement.

NOTE This includes defining technical and quality measures and critical performance parameters associated with each effectiveness measure identified in the stakeholder requirements. The critical performance measures (e.g., measures of effectiveness and measures of suitability) are defined, analyzed and reviewed to help ensure stakeholder requirements are met and to help ensure identification of project cost, schedule or performance risk associated with any non-compliance. ISO/IEC 15939 (IEEE Std 15939-2007) provides a process to identify, define and use appropriate measures. INCOSE TP-2003-020-01, *Technical Measurement*, provides information on the selection, definition and implementation of critical performance measures. The ISO/IEC 25000 series of standards provides relevant quality measures.

1. Feed back the analyzed requirements to applicable stakeholders to validate that their needs and expectations have been adequately captured and expressed.
2. Resolve stakeholder requirements issues.

NOTE This includes requirements that violate the characteristics for individual requirements or the set of requirements as defined in ISO/IEC/IEEE 29148.

1. **Manage the stakeholder needs and requirements definition.** This activity consists of the followingtasks:
2. Obtain explicit agreement on the stakeholder requirements.

NOTE This includes confirming that stakeholder requirements are expressed correctly, comprehensible to originators, and that the resolution of conflict in the requirements has not corrupted or compromised stakeholder intentions.

1. Maintain traceability of stakeholder needs and requirements.

NOTE Through the life cycle, bi-directional traceability is maintained between the stakeholder needs and requirements and the stakeholders and sources, organizational strategy, and business and mission problems and opportunities. Additional traceability to systems making up the system solution facilitates the transition to the System Requirements Definition process. This is often facilitated by an appropriate data repository.

1. Provide key information items that have been selected for baselines.

NOTE The Configuration Management process is used to establish and maintain configuration items and baselines. This process (Stakeholder Needs and Requirements Definition) identifies candidates for the baseline, and then provides the information items to CM. For this process, the stakeholder needs, stakeholder requirements, and operational concept are typical information items that are baselined.

**6.4.3** **System requirements definition process**

**6.4.3.1** **Purpose**

The purpose of the System Requirements Definition process is to transform the stakeholder, user-oriented view of desired capabilities into a technical view of a solution that meets the operational needs of the user.

This process creates a set of measurable system requirements that specify, from the supplier’s perspective, what characteristics, attributes, and functional and performance requirements the system is to possess, in order to satisfy stakeholder requirements. As far as constraints permit, the requirements should not imply any specific implementation.

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**6.4.3.2 Outcomes**

As a result of the successful implementation of the System Requirements Definition process:

1. The system description, including system interfaces, functions and boundaries, for a system solution is defined.
2. System requirements (functional, performance, process, non-functional, and interface) and design constraints are defined.
3. Critical performance measures are defined.
4. The system requirements are analyzed.
5. Any enabling systems or services needed for system requirements definition are available.
6. Traceability of system requirements to stakeholder requirements is developed.

**6.4.3.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the System Requirements Definition process.

a) **Prepare for system requirements definition.** This activity consists of the following tasks:

1. Define the functional boundary of the system in terms of the behavior and properties to be provided.

NOTE The functional boundary definition is partly based on the context of use and operational scenarios defined in the frame of the Stakeholder Needs and Requirements Definition process. This includes the system’s stimuli and its responses to user and environment behavior, and an analysis and description of the required interactions between the system and its environment in terms of interface properties and constraints, such as mechanical, electrical, mass, thermal, data, and procedural flows. This establishes the expected system behavior, expressed in quantitative terms, at its boundary.

1. Define the system requirements definition strategy.

NOTE This includes the approach to be used to identify and define the system requirements, and manage the requirements through the life cycle.

1. Identify and plan for the necessary enabling systems or services needed to support system requirements definition.

NOTE This includes identification of requirements and interfaces for the enabling systems. Enabling systems for system requirements definition include tools for facilitation and requirements management.

1. Obtain or acquire access to the enabling systems or services to be used.

NOTE The Validation process is used to objectively confirm that the enabling system achieves its intended use for its enabling functions.

b) **Define system requirements.** This activity consists of the following tasks:

1. Define each function that the system is required to perform.

NOTE 1 This includes how well the system, including its operators, is required to perform that function, the conditions under which the system is to be capable of performing the function, the conditions under which the system is to commence performing that function and the conditions under which the system is to cease performing that function. In some cases, functions are derived from analysis of critical quality characteristics (e.g., system diagnosing function or highly frequent data backup function for reliability).

NOTE 2 Conditions for the performance of functions can incorporate reference to required states and modes of operation of the system. System requirements depend heavily on abstract representations of proposed system characteristics and sometimes employ multiple modeling techniques and perspectives to give a sufficiently complete description of the desired system requirements.

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NOTE 3 Enabling functions that are required to support the system-of-interest in achieving its functionality are also identified and defined concurrently with the function of the system-of-interest. This is necessary to help ensure that the enabling functions are identified and accounted for.

1. Define necessary implementation constraints.

NOTE This includes the implementation decisions that are allocated from architecture definition at higher levels in the structure of the system and are introduced by stakeholder requirements or are solution limitations.

1. Identify system requirements that relate to risks, criticality of the system, or critical quality characteristics.

NOTE Critical quality characteristics commonly include those related to health, safety, security assurance, reliability, availability and supportability. This includes analysis and definition of safety considerations, including those relating to methods of operation and maintenance, environmental influences and personnel injury. It also includes helping to ensure each safety related function and its associated safety integrity, is expressed in terms of the necessary risk reduction, and is specified and allocated to designated safety-related systems. Applicable standards are used concerning functional safety, e.g., IEC 61508, and environmental protection, e.g., ISO 14001. Analyze security considerations including those related to compromise and protection of sensitive information, data and material. The security-related risks are defined, including, but not limited to, administrative, personnel, physical, computer, communication, network, emission and environment factors using, as appropriate, applicable security standards. Refer to ISO/IEC/IEEE 15026-4 for system and software assurance guidance. ISO/IEC 27036 provides guidance for information security requirements for the outsourcing of products and services. ISO 25030 provides guidance for external system quality factors and characteristics. For systems intended for human interaction, human-factors engineering (ergonomics) specifications are considered. For systems that have usability requirements, recommendations for obtaining a desired level of usability can be found in ISO TR 18529, Ergonomics—Ergonomics of human-system interaction—Human-centred life cycle process descriptions.

1. Define system requirements and rationale.

NOTE 1 This includes defining system requirements consistent with stakeholder requirements, functional boundaries, functions, constraints, cost targets, identified interfaces, and critical quality characteristics. Consistent practice has shown this process requires iterative and recursive steps in parallel with other life cycle processes through the system hierarchy. See ISO/IEC/IEEE 29148 clauses 5 and 6 for more information on system requirements, and clauses 8 and 9 for a description of and an annotated outline for a System Requirements Specification.

NOTE 2 The system requirements are recorded in a form suitable for requirements management through the life cycle. These records establish the system requirements baseline, and include the associated rationale, decisions and assumptions. They are the basis for traceability to information items and subsequent system elements. Change requests of system requirements also provide rationale to help in the determination of the acceptability of the proposed change, including consistency with stakeholder requirements.

NOTE 3 The System Analysis Process is used to determine appropriate values for requirement parameters, considering the estimated cost, schedule, and technical performance of the system. The Validation Process is used to determine if the requirements address the stakeholders’ needs. The Verification Process determines the quality of the requirements with respect to the attributes and characteristics of good requirements (refer to ISO/IEC/IEEE 29148).

c) **Analyze system requirements.** This activity consists of the following tasks:

1. Analyze the complete set of system requirements.

NOTE 1 System requirements are analyzed for characteristics of individual requirements, as well as characteristics of the set of requirements. Potential analysis characteristics include that the requirements are necessary, implementation free, unambiguous, consistent, complete, singular, feasible, traceable, verifiable, affordable, and bounded. ISO/IEC/IEEE 29148 provides additional information on characteristics of requirements. Deficiencies, conflicts and weaknesses are identified and resolved within the complete set of system requirements.

NOTE 2 The System Analysis process is used to assess feasibility, affordability, and balance.

1. Define critical performance measures that enable the assessment of technical achievement.

NOTE This includes defining technical and quality measures and critical performance parameters associated with each effectiveness measure identified in the system requirements. The critical performance measures (e.g., measures of performance and technical performance measures) are analyzed and reviewed to help ensure system requirements

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are met and to help ensure identification of project cost, schedule or performance risk associated with any non-compliance. ISO/IEC 15939 (IEEE Std 15939-2007) provides a process to identify, define and use appropriate measures. INCOSE TP-2003-020-01*, Technical Measurement*, provides information on the selection, definition and implementation of critical performance measures. The ISO/IEC 25000 series of standards provides relevant quality measures.

1. Feed back the analyzed requirements to applicable stakeholders for review.

NOTE Feedback helps ensure that the specified system requirements have been adequately captured and expressed. Confirmation is made that they are a necessary and sufficient response to stakeholder requirements and a necessary and sufficient input to other processes, in particular architecture and design. This is one application of the Validation Process applied for the specific requirements.

1. Resolve system requirements issues.

NOTE This includes requirements that violate the characteristics for individual requirements or the set of requirements as defined in ISO/IEC/IEEE 29148.

d) **Manage system requirements.** This activity consists of the following tasks:

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NOTE Maintaining system requirements includes defining, recording, and controlling the baseline, generally under formal configuration management, along with managing any changes resulting from the application of other life cycle processes such as architecture or design.

1. Obtain explicit agreement on the system requirements.

NOTE This includes confirming that system requirements are expressed correctly, comprehensible to originators, and that the resolution of conflict in the requirements has not corrupted or compromised stakeholder intentions.

1. Maintain traceability of the system requirements.

NOTE Through the life cycle, bi-directional traceability is maintained between the system requirements and the stakeholder requirements, architecture elements, interface definitions, analysis results, verification methods or techniques, and allocated, decomposed, and derived requirements. This helps ensure that all achievable stakeholder requirements are met by one or more system requirements, and all system requirements meet or contribute to meeting at least one stakeholder requirement. This is often facilitated by an appropriate data repository.

1. Provide key information items that have been selected for baselines.

NOTE The Configuration Management process is used to establish and maintain configuration items and baselines. This process (System Requirements Definition) identifies candidates for the baseline, and then provides the information items to CM. For this process, the system requirements are typical information items that are baselined.

**6.4.4 Architecture definition process**

**6.4.4.1** **Purpose**

The purpose of the Architecture Definition process is to generate system architecture alternatives, to select one or more alternative(s) that frame stakeholder concerns and meet system requirements, and to express this in a set of consistent views.

Iteration of the Architecture Definition process with the Business or Mission Analysis process, System Requirements Definition process, Design Definition process, and Stakeholder Needs and Requirements Definition process is often employed so that there is a negotiated understanding of the problem to be solved and a satisfactory solution is identified. The results of the Architecture Definition process are widely used across the life cycle processes. Architecture definition may be applied at many levels of abstraction, highlighting the relevant detail that is necessary for the decisions at that level.

NOTE 1 System architecture deals with fundamental principles, concepts, properties, and characteristics and their incorporation into the system-of-interest. Architecture definition has more uses than as merely a driver (or part of) design. Refer to ISO/IEC/IEEE 42010:2011 for more information about architecture description and the uses and nature of architecture.

NOTE 2 The Architecture Definition process supports identification of stakeholders and their concerns. As the process unfolds, insights are gained into the relation between the requirements specified for the system and the emergent

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properties and behaviors of the system that arise from the interactions and relations between the system elements. The Design Definition process (see subclause 6.4.5), on the other hand, is driven by requirements that have been vetted through the architecture and more detailed analyses of feasibility. Architecture focuses on suitability, viability, and desirability, whereas design focuses on compatibility with technologies and other design elements and feasibility of construction and integration. An effective architecture is as design-agnostic as possible to allow for maximum flexibility in the design trade space. An effective architecture also highlights and supports trade-offs for the Design Definition process and possibly other processes such as Portfolio Management, Project Planning, System Requirements Definition, and Verification.

NOTE 3 In product line architectures, the architecture is necessarily spanning across several designs. The architecture serves to make the product line cohesive and helps ensure compatibility and interoperability across the product line. Even for a single product system, the design of the product will likely change over time while the architecture remains constant.

**6.4.4.2 Outcomes**

As a result of the successful implementation of the Architecture Definition process:

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| a) | Identified stakeholder concerns are addressed by the architecture. |
| b) | Architecture viewpoints are developed. |
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| c) | -`-`,,`,,,`,``,,,`,`,``,``,,,,,,` |
| Context, boundaries, and external interfaces of the system are defined. |
| d) | Architecture views and models of the system are developed. |
| e) | Concepts, properties, characteristics, behaviors, functions, or constraints that are significant to |
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|  | architecture decisions of the system are allocated to architectural entities. |
| f) | System elements and their interfaces are identified. |
| g) | Architecture candidates are assessed. |
| h) | An architectural basis for processes throughout the life cycle is achieved. |
| i) | Alignment of the architecture with requirements and design characteristics is achieved. |
| j) | Any enabling systems or services needed for architecture definition are available. |
| k) | Traceability of architecture elements to stakeholder and system requirements is developed. |

**6.4.4.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Architecture Definition process.

a) **Prepare for architecture definition.** This activity consists of the following tasks:

1. Review pertinent information and identify key drivers of the architecture.

NOTE Key drivers are identified by reviewing: (a) market studies, industry projections, competitor product plans, and scientific findings; (b) organizational strategies, organizational-level concept of operations, organizational policies and directives, regulatory and legal constraints, and stakeholder requirements; (c) mission or business concept of operations, system operational concept, operational environment, technology roadmaps, and system requirements; and (d) any other factors that impact the suitability of the system through its life cycle.

1. Identify stakeholder concerns.

NOTE Stakeholders are initially identified in the Stakeholder Needs and Requirements process. Additional stakeholders are usually identified during the Architecture Definition process. 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. This also includes concerns

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that the system will be compromised intentionally or unintentionally via a threat agent or accidentally via a safety hazard.

1. Define the architecture definition roadmap, approach, and strategy.

NOTE This includes the identification of stakeholder engagement opportunities, the definition of architecture review activities, evaluation approach and criteria, measurement approach, and measurement methods (refer to the Measurement process). The roadmap shows how the architecture will evolve to an envisioned end state and often has a longer timeframe than for the current system-of-interest. The approach is the manner in which the work will be accomplished, such as how to engage with stakeholders, how to vet the results, or where to do the work. The strategy deals with the systematic plan of action for implementing the approach consistent with the roadmap.

1. Define evaluation criteria based on stakeholder concerns and key requirements.
2. Identify and plan for the necessary enabling systems or services needed to support the Architecture Definition process.

NOTE This includes identification of requirements and interfaces for the enabling system. Enabling systems for architecture definition include tools for collaboration and architecture development, and architecture reuse repositories (for architecture patterns, architecture artifacts, reference architectures, etc.).

1. Obtain or acquire access to the enabling systems or services to be used.

NOTE The Validation process is used to objectively confirm that the enabling system achieves its intended use for its enabling functions.

1. **Develop architecture viewpoints.** This activity consists of the following tasks:
   1. Select, adapt, or develop viewpoints and model kinds based on stakeholder concerns.
   2. Establish or identify potential architecture framework(s) to be used in developing models and views.

NOTE Some architecture frameworks identify stakeholders and their concerns, and relevant viewpoints that address those concerns, while other architecture frameworks are more general in their guidance. Viewpoints specify the kinds of models to be used and how the resulting models can be used to generate architecture views. Refer to ISO/IEC/IEEE 42010 for more information on architecture framework and architecture description practices.

* 1. Capture rationale for selection of framework(s), viewpoints and model types.
  2. Select or develop supporting modeling techniques and tools.

1. **Develop models and views of candidate architectures.** This activity consists of the following tasks:
   1. Define the system context and boundaries in terms of interfaces and interactions with external entities.

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|  | NOTE | This task is mainly based on the outcomes of the Business or Mission Analysis process, and is performed | | |
|  | concurrently with the Stakeholder Needs and Requirements Definition process. It consists of identifying the entities | | | |
|  | external to the system (i.e., existing and projected systems, products, and services that constitute the system context) | | | |
|  | and defining the boundaries of the system (i.e., interactions with these external entities through the interfaces that--- | | | |
|  | cross the boundaries). The external entities could include the necessary enabling systems. The Architecture | | | |
|  | Definition process defines interfaces to the extent needed to support essential architectural decisions and`,,`,,`,`,,` | | | |
|  | understanding. These interface definitions are then refined by the Design Definition process. | | | -`- |
|  | 2) |  |  | --`,,`,,,`,``,,,`,`,``,``,,,,,,` |
|  | Identify architectural entities and relationships between entities that address key stakeholder | | |
|  | concerns and critical system requirements. | | |  |
|  | NOTE | Architecture is not necessarily concerned with all requirements, but rather only with those that drive the | | |
|  | architecture. On the other hand, the Design Definition process takes into account all the requirements. Sometimes, | | | |
|  | through the Architecture Definition process there will be requirements that are deemed to be inappropriate, | | | |
|  | unaffordable, or unsuitable. These are requirements issues that are resolved through iteration of the System | | | |
|  | Requirements Definition process. It is also important that the architecture addresses key stakeholder concerns since | | | |
|  | not all of these will be captured in requirements. | |  |  |
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1. Allocate concepts, properties, characteristics, behaviors, functions, or constraints that are significant to architecture decisions of the system to architectural entities.

NOTE The items being allocated to could be physical, logical, or conceptual.

1. Select, adapt, or develop models of the candidate architectures of the system.

NOTE It is common to use models in architecture definition. The models used are those that best address key stakeholder concerns. Refer to ISO/IEC/IEEE 42010 for how this can be done. Historically, it has been common to use logical and physical models in architecture definition. Information on logical, physical, and other models is provided in Annex F.

1. Compose views from the models in accordance with identified viewpoints to express how the architecture addresses stakeholder concerns and meets stakeholder and system requirements.
2. Harmonize the architecture models and views with each other.

NOTE Correspondence rules from frameworks are one way to establish harmony between views. See ISO/IEC/IEEE 42010.

d) **Relate the architecture to design.** This activity consists of the following tasks:

1. Identify system elements that relate to architectural entities and the nature of these relationships.

NOTE Sometimes the system elements are initially notional until Design Definition has occurred since this depends on the actual design(s) to be done. Sometimes a “reference architecture” is created using these notional system elements as a means to convey architectural intent and to check for design feasibility.

1. Define the interfaces and interactions between the system elements and with external entities.

NOTE This is defined at level of detail necessary to convey the architectural intent and can be further refined in the Design Definition process.

* 1. Partition, align and allocate requirements to architectural entities and system elements.
  2. Map system elements and architectural entities to design characteristics.
  3. Define principles for the system design and evolution.

1. **Assess architecture candidates.** This activity consists of the following tasks:
   1. Assess each candidate architecture against constraints and requirements.
   2. Assess each candidate architecture against stakeholder concerns using evaluation criteria.

NOTE The System Analysis process and the Risk Management process can be used to support this task.

1. Select the preferred architecture(s) and capture key decisions and rationale.

NOTE The Decision Management process can be used to support this task.

1. Establish the architecture baseline of the selected architecture.

NOTE The architecture baseline is composed of models, views and other relevant architecture descriptions.

1. **Manage the selected architecture.** This activity consists of the following tasks:
   1. Formalize the architecture governance approach and specify governance related roles and responsibilities, accountabilities, and authorities (related to design, quality, security, safety, etc.).
   2. Obtain explicit acceptance of the architecture by stakeholders.

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NOTE 1 The Verification and Validation processes are used to confirm that the architecture models and views reflect stakeholder and system requirements.

NOTE 2 In some applications it is necessary to certify the architecture. Certification confirms that the architectural intent is met, the architectural vision and key concepts are correctly implemented, and stakeholder concerns are properly addressed. It also gives essential feedback to the Architecture Definition process to help in the learning process and to help ensure that future iterations of architecture better address stakeholder concerns.

1. Maintain concordance and completeness of the architectural entities and their architectural characteristics.

NOTE The entities to be checked are not only technical. These are also, for example, legal, economical, organizational and operational entities that are normally part of stakeholder requirements and concerns.

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1. Organize, assess and control evolution of the architecture models and views.
2. Maintain the architecture definition and evaluation strategy.

NOTE This includes updating the architecture based upon technological, implementation, operational experiences, as well as the management of external and internal interfaces that are defined at this level of system decomposition.

1. Maintain traceability of the architecture.

NOTE Through the life cycle, bi-directional traceability is maintained between the architecture entities (models,

views, and viewpoints) to the requirements (including allocated, decomposed, and derived), interface definitions, analysis results, and verification methods or techniques. If possible, traceability is also maintained between the architecture entities and the stakeholder concerns.

1. Provide key information items that have been selected for baselines.

NOTE The Configuration Management process is used to establish and maintain configuration items and baselines. This process (Architecture Definition) identifies candidates for the baseline, and then provides the information items to CM.

**6.4.5** **Design definition process**

**6.4.5.1** **Purpose**

The purpose of the Design Definition process is to provide sufficient detailed data and information about the system and its elements to enable the implementation consistent with architectural entities as defined in models and views of the system architecture.

NOTE 1 The Architecture Definition process, supports identification of stakeholders and their concerns. Through the use of the process, insights are gained into the relation between the requirements specified for the system and the emergent properties and behaviors of the system that arise from the interactions and relations between the system elements. The Design Definition process, on the other hand, is driven by requirements that have been vetted through the architecture and more detailed analyses of feasibility. Architecture focuses on suitability, viability, and desirability, whereas design focuses on compatibility with technologies and other design elements and feasibility of construction and integration. An effective architecture is as design-agnostic as possible to allow for maximum flexibility in the design trade space.

NOTE 2 Design definition considers any applicable technologies and their contribution to the system solution. Design provides the ‘implement-to’ level of the definition, such as drawings and detailed design descriptions.

NOTE 3 This process provides feedback to the system architecture to consolidate or confirm the allocation, partitioning and alignment of architectural entities to system elements that compose the system.

**6.4.5.2 Outcomes**

As a result of the successful implementation of the Design Definition process:

1. Design characteristics of each system element are defined.
2. System requirements are allocated to system elements.
3. Design enablers necessary for design definition are selected or defined.

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1. Interfaces between system elements composing the system are defined or refined.
2. Design alternatives for system elements are assessed.
3. Design artifacts are developed.
4. Any enabling systems or services needed for design definition are available.
5. Traceability of the design characteristics to the architectural entities of the system architecture is established.

**6.4.5.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Design Definition process.

a) **Prepare for design definition.** This activity consists of the following tasks:

1. Determine technologies required for each system element composing the system.

NOTE Several technologies are sometimes used for a given system element (e.g., mechanics, electronics, software, operator roles, etc.).

1. Determine the necessary design characteristics types.

NOTE For each technology the necessary design characteristics types (e.g., detailed patterns, structures, size, volume, gauge, template, etc.) are defined. Design characteristics include security considerations such as the principle of least privilege, layered defenses, restricted access to system services, and other considerations to minimize and defend the system attack surface.

1. Define principles for evolution of the design.

NOTE This includes defining periodic assessment of the design characteristics in case of evolution of the system and of its architecture as well as forecasting potential obsolescence of system elements and technologies, their replacement by others over time in the system life cycle, and the consequences for the design definition.

1. Define the design definition strategy.
2. Identify and plan for the necessary enabling systems or services needed to support design definition.

NOTE This includes identification of requirements and interfaces for the enabling systems. Enabling systems for design definition include tools for collaboration and design development, and design reuse repositories (for design patterns, design artifacts, design standards, etc.).

1. Obtain or acquire access to the enabling systems or services to be used.

NOTE The Validation process is used to objectively confirm that the enabling system achieves its intended use for its enabling functions.

1. **Establish design characteristics and design enablers related to each system element.** This activityconsists of the following tasks:
2. Allocate system requirements to system elements.

NOTE Some of the system requirements may have already been allocated to system elements during architecture definition. The purpose of this task is to complete the allocation to the extent necessary to address all system requirements.

1. Transform architectural characteristics into design characteristics.

NOTE This task transforms each architectural characteristic related to architectural entities assigned to the system element into design characteristics (dimensions, shapes, materials, critical quality characteristics, data processing

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structures, etc.) using adequate representation such as drawings, diagrams, models, architectures, tables of metrics and their values, etc.; every data is associated with detailed acceptable margins for implementation (if relevant at this step).

1. Define the necessary design enablers.

NOTE This task defines and/or selects the necessary design enablers such as models, equations, algorithms, calculations, formal expressions and values of parameters, patterns, heuristics, etc. that are associated to design characteristics. Compatibility, affordability, security, and other critical properties in the context of their planned operational environment are considerations during the definition of necessary design enablers. ISO 9241-210 provides human centered design/ergonomic design guidelines.

1. Examine design alternatives.

NOTE Assess the feasibility of design characteristics and perform trades in the architecture or requirements when design characteristics cannot be implemented.

1. Refine or define the interfaces between the system elements and with external entities.

NOTE Interfaces are identified and defined in the Architecture Definition process to the level or extent needed for the architecture intent and understanding. They are refined in Design Definition process based on the design characteristics, interfaces and interactions of the system element with other system elements composing the system and with external entities. Additional interfaces might need to be identified and defined that were not addressed in the architecture definition.

1. Establish the design artifacts.

NOTE This task formalizes the design characteristics of the system element through dedicated artifacts depending on the implementation technology. Examples of artifacts include data sheets (electronics), databases (software), documents (operator role), and exportable data files (mechanics).

1. **Assess alternatives for obtaining system elements.** This activity consists of the following tasks:
2. Identify any candidate Non-Developmental-Items (NDI) that may be considered for use.

NOTE This includes COTS (Commercial-Off-The-Shelf), reuse of a previous design, or acquirer provided items.

1. Assess each candidate NDI and new design alternative against criteria developed from expected design characteristics or system element requirements to determine suitability for the intended application.
2. Determine the preferred alternative among any candidate NDI solutions and new design alternatives for a system element.

NOTE The System Analysis process is used for analyses or assessments, as well as the Decision Management process to perform the selection.

d) **Manage the design.** This activity consists of the following tasks:

1. Map design characteristics up to the system elements.

NOTE 1 This task consists of establishing traceability between the detailed design characteristics and the architectural entities of the system architecture.

NOTE 2 This facilitates providing feedback to the Architecture Definition process to possibly modify the physical arrangement of system elements in order to obtain architectural characteristics (e.g., modularity, usability, inter-operability, safeguard, etc.) as expected for the parent system architecture to meet stakeholder concerns.

1. Capture design and rationale

NOTE 1 Rationale includes information about major implementation options and enablers.

NOTE 2 The Verification and Validation processes are invoked to verify and validate each detailed design characteristic and implementation option.

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1. Maintain traceability of design.

NOTE Through the life cycle, bi-directional traceability is maintained between the design characteristics and the architectural entities, identified interfaces, analysis results, verification methods or techniques, and system element requirements.

1. Provide key information items that have been selected for baselines.

NOTE The Configuration Management process is used to establish and maintain configuration items and baselines.

This process (Design Definition) identifies candidates for the baseline, and then provides the information items to CM.

**6.4.6 System analysis process**

**6.4.6.1** **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 process applies to the development of inputs needed for any technical assessment. It can provide confidence in the utility and integrity of system requirements, architecture, and design. System analysis covers a wide range of differing analytic functions, levels of complexity, and levels of rigor. It includes mathematical analysis, modeling, simulation, experimentation, and other techniques to analyze technical performance, system behavior, feasibility, affordability, critical quality characteristics, technical risks, life cycle costs, and to perform sensitivity analysis of the potential range of values for parameters across all life cycle stages. It is used for a wide range of analytical needs concerning operational concepts, determination of requirement values, resolution of requirements conflicts, assessment of alternative architectures or system elements, and evaluation of engineering strategies (integration, verification, validation, and maintenance). Formality and rigor of the analysis will depend on the criticality of the information need or work product supported, the amount of information/data available, the size of the project, and the schedule for the results.

NOTE This process is often used in conjunction with the Decision Management process.

**6.4.6.2 Outcomes**

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| -- | System analysis assumptions and results are validated. |
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| a result of the successful implementation of the System Analysis process: | |
|  | System analyses needed are identified. |
| `,,`,,`,`,,` | System analysis results are provided for decisions. |
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1. Any enabling systems or services needed for system analysis are available.
2. Traceability of the system analysis results is established.

**6.4.6.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the System Analysis process.

a) **Prepare for system analysis**. This activity consists of the following tasks:

1. Identify the problem or question that requires system analysis.

NOTE This includes technical, functional, and non-functional objectives of the analysis. Non-functional objectives include critical quality characteristics, various properties, technology maturity, manufacturing maturity, technical risks, etc. The problem statement or question to be answered by the analysis is essential to establish the objectives of the analysis and the expectations and utility of the results.

1. Identify the stakeholders of the system analysis.

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1. Define the scope, objectives, and level of fidelity of the system analysis.

NOTE The necessary level of fidelity (accuracy or precision) is a factor in determining the appropriate level of rigor.

1. Select the system analysis methods.

NOTE The methods are chosen based on time, cost, fidelity, technical drivers, and criticality of analysis. Analysis methods have a wide range of levels of rigor and include expert judgment, “back of the envelope” calculation, spreadsheet computations, historical data and trend analysis, engineering models, simulation, visualization, and prototyping. Due to cost and schedule constraints, most systems only perform system analysis for critical characteristics.

1. Define the system analysis strategy.
2. Identify and plan for the necessary enabling systems or services needed to support system analysis.

NOTE This includes identification of requirements and interfaces for the enabling systems. The system analysis enabling systems include the tools, relevant models, and potential data repositories needed to support the analysis. The methods chosen will be a major factor in determining what tools are appropriate to support the analysis. This also includes determining the availability of relevant models and data.

1. Obtain or acquire access to the enabling systems or services to be used.

NOTE The Validation process is used to objectively confirm that the enabling system achieves its intended use for its enabling functions.

* 1. Collect the data and inputs needed for the analysis.

1. **Perform system analysis**. This activity consists of the following tasks:
   1. Identify and validate assumptions.
   2. Apply the selected analysis methods to perform the required system analysis.
   3. Review the analysis results for quality and validity.

NOTE The results are coordinated with associated analyses that have been previously completed.

1. Establish conclusions and recommendations.

NOTE The appropriate subject matter experts and stakeholders are identified and engaged in this task.

* 1. Record the results of the system analysis,

1. **Manage system analysis**. This activity consists of the following tasks:
   1. Maintain traceability of system analysis results.

NOTE Through the life cycle, bi-directional traceability is maintained between the system analysis results and any system definition item for which the analysis is supporting a decision or providing rationale (e.g., system requirement values, architecture alternatives). This is often facilitated by an appropriate data repository.

1. Provide key information items that have been selected for baselines.

NOTE The Configuration Management process is used to establish and maintain configuration items and baselines.

This process (System Analysis) identifies candidates for the baseline, and then provides the information items to CM.

For this process, the analysis results or reports are typical information items that are baselined.

**6.4.7** **Implementation process**

**6.4.7.1** **Purpose**

The purpose of the Implementation process is to realize a specified system element.

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This process transforms requirements, architecture, and design, including interfaces, into actions that create a system element according to the practices of the selected implementation technology, using appropriate technical specialties or disciplines. This process results in a system element that satisfies specified system requirements (including allocated and derived requirements), architecture, and design.

NOTE This applies to both a single element (concept and development stage) and production run (as in production stage). It also can apply in the resolution of changes needed in the Support stage.

**6.4.7.2 Outcomes**

As a result of the successful implementation of the Implementation process:

1. Implementation constraints that influence the requirements, architecture, or design are identified.
2. A system element is realized.
3. A system element is packaged or stored.
4. Any enabling systems or services needed for implementation are available.
5. Traceability is established.

**6.4.7.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Implementation process.

a) **Prepare for implementation.** This activity consists of the following tasks:

1. Define an implementation strategy.

NOTE 1 Implementation strategies include build new, acquire new, or re-use existing elements (with or without modification), If the strategy is reuse, then the project will need to determine the level, source, and suitability of the reused system elements. The implementation strategy includes implementation procedures, fabrication processes, tools and equipment, implementation tolerances and verification uncertainties. In the case of repeated system element implementation (e.g., mass production, replacement system elements) the implementation procedures and fabrication processes are defined to achieve consistent and repeatable producibility.

NOTE 2 The implementation strategy often invokes the Agreement processes, or requires enabling systems and services that include specialized life cycle development and support environments.

1. Identify constraints from the implementation strategy and implementation technology on the system requirements, architecture characteristics, design characteristics, or implementation techniques.

NOTE This includes current or anticipated limitations of the chosen implementation technology, acquirer furnished materials or system elements for adaptation and limitations resulting from the use of required implementation enabling systems.

1. Identify and plan for the necessary enabling systems or services needed to support implementation.

NOTE This includes identification of requirements and interfaces for the enabling systems.

1. Obtain or acquire access to the enabling systems or services, and materials to be used.

NOTE The Validation process is used to objectively confirm that the integration enabling system achieves its intended use for its enabling functions.

b) **Perform implementation.** This activity consists of the following tasks:

NOTE Throughout the Implementation process the Verification process is used to objectively confirm the system

element's conformance to requirements and the product's quality characteristics. The Validation process is used to

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objectively confirm the element is ready to be used in its intended operational environment according to stakeholder requirements.

1. Realize or adapt system elements, according to the strategy, constraints, and defined implementation procedures.

NOTE This is done using the implementation enabling systems and specified resources. Realizing system elements may include developing or purchasing them. Adaptation includes configuration of system elements that are reused or modified. Realization or adaptation is conducted with regard to standards that govern applicable safety, security, privacy and environmental guidelines or legislation and the practices of the relevant implementation technology.

1. Hardware

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Hardware elements are either acquired or fabricated. Hardware elements are fabricated using applicable techniques relevant to the physical implementation technology and materials selected. As appropriate, hardware elements are verified for conformance to specified system requirements and critical quality characteristics.

1. Software

System elements realized in software are either acquired or developed. As appropriate, these elements are verified for conformance to the system requirements and design criteria. ISO/IEC/IEEE 12207 applies to system elements realized in software.

1. Services

Service elements include a set of services to be provided. As appropriate, service elements are verified for conformance to the system requirements and service criteria. ISO/IEC 20000-1:2011 (IEEE Std 20000-1:2013), applies to system elements realized in services.

1. Utilization and Support Resources

Other system elements include utilization and support resources such as operational procedures, maintenance procedures, user training, etc. As appropriate, utilization and support resource elements are verified for conformance to the system requirements and operational concept.

1. Package and store the system element.

NOTE Contain the system element in order to achieve continuance of its characteristics. Conveyance and storage, and their durations, influence the specified containment. Final configuration and product information is captured by the Configuration Mgt and Information Mgt processes when the system element is stored.

1. Record objective evidence that the system element meets system requirements.

NOTE Evidence is provided in accordance with supply agreements, legislation and organization policy. Evidence includes element modifications made due to processing changes or any non-conformances found during the Verification and Validation Processes. The objective evidence is part of the system element's as-implemented configuration baseline established through the Configuration Management process and includes the results of unit testing, analysis, inspections, walk-through events, demonstrations, product or technical reviews, or other verification exercises.

c) **Manage results of implementation.** This activity consists of the following tasks:

1. Record implementation results and any anomalies encountered.

NOTE This includes anomalies due to the implementation strategy, the implementation enabling systems, or incorrect system definition. The Project Assessment and Control process is used to analyze the data to identify the root cause, enable corrective or improvement actions, and to record lessons learned.

1. Maintain traceability of the implemented system elements.

NOTE Bi-directional traceability is maintained between the implemented system elements and the system

architecture, design, and system requirements including interface requirements and definitions that are necessary for

implementation.

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1. Provide key information items that have been selected for baselines.

NOTE The Configuration Management process is used to establish and maintain configuration items and baselines. This process (Implementation) identifies candidates for the baseline, and then provides the information items to CM. For this process, the system elements are typical information items that are baselined.

**6.4.8 Integration process**

**6.4.8.1** **Purpose**

The purpose of the Integration process is to synthesize a set of system elements into a realized system (product or service) that satisfies system requirements, architecture, and design.

This process assembles the implemented system elements. Interfaces are identified and activated to enable interoperation of the system elements as intended. This process integrates the enabling systems with the system-of-interest to facilitate interoperation.

NOTE 1 For a given level of the system hierarchy, this process iteratively combines implemented system elements to form complete or partial system configurations in order to build a product or service. It is used recursively for successive levels of the system hierarchy.

NOTE 2 The interfaces are defined by the Architecture Definition and Design Definition processes. This process coordinates with these other processes and checks to make sure the interface definitions are adequate and that they take into account the integration needs.

**6.4.8.2 Outcomes**

As a result of the successful implementation of the Integration process:

1. Integration constraints that influence system requirements, architecture, or design, including interfaces, are identified.
2. Approach and checkpoints for the correct operation of the assembled interfaces and system functions are defined.
3. Any enabling systems or services needed for integration are available.
4. A system composed of implemented system elements is integrated.
5. The interfaces between the implemented system elements that compose the system are checked.
6. The interfaces between the system and the external environment are checked.
7. Integration results and anomalies are identified.
8. Traceability of the integrated system elements is established.

**6.4.8.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Integration process.

a) **Prepare for integration.** This activity consists of the following tasks:

1. Identify and define check points for the correct operation and integrity of the assembled interfaces and the selected system functions.

NOTE 1 Detailed verification of the interfaces is performed using the Verification process.

NOTE 2 Refer to ISO/IEC/IEEE 15026 and the ISO/IEC 27000 series for information on assurance, integrity, and security. Consider anti-counterfeit, anti-tamper, system and software assurance and interoperability elements when identifying and defining checkpoints.

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1. Define the integration strategy

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NOTE 1 The integration is performed according to a predefined integration strategy that sequences the order for assembling the implemented system elements based on the priorities of the system requirements and architecture definition focusing on the interfaces, while minimizing integration time, cost, and risks.

NOTE 2 This strategy often provides for verification against a sequence of progressively more complete system element configurations. It is dependent on system element availability and is consistent with a fault isolation and diagnosis strategy. Wherever possible, an integrated configuration includes its human operators. Successive applications of the Integration process and the Verification process, and when appropriate the Validation process, are repeated for systems at successive levels until the system-of-interest has been realized.

1. Identify and plan for the necessary enabling systems or services needed to support integration.

NOTE This includes identification of requirements and interfaces for the enabling systems. Enabling systems for integration include the integration facilities, assembly equipment, training systems, discrepancy reporting systems, simulators, measurement devices, and facility security. Changes needed for the enabling systems to support the integration tasks need to be identified and defined. The need for these changes are provided to the stakeholders that govern the enabling systems.

1. Obtain or acquire access to the enabling systems or services, and materials to be used.

NOTE The Validation process is used to objectively confirm that the integration enabling system achieves its intended use for its enabling functions.

1. Identify system constraints from integration to be incorporated in the system requirements, architecture or design.

NOTE This includes requirements such as accessibility, safety for integrators, required interconnections for sets of implemented system elements and for enablers, and interface constraints.

1. **Perform integration - Successively integrate system element configurations until the complete system is synthesized.** This activity consists of the following tasks:
2. Obtain implemented system elements in accordance with agreed schedules.

NOTE The implemented system elements are received from suppliers, the acquirer, or withdrawn from storage. System elements are handled in accordance with relevant health, safety, security and privacy considerations. As part of the acceptance of the implemented system elements, each element is checked to help ensure it has been verified and validated against acceptance criteria specified in an agreement. The delivered configuration, conformance, compatibility of interfaces, the presence of mandatory information items are checked. Implemented system elements that do not pass verification are identified as such and handled in accordance with defined procedures.

1. Assemble the implemented system elements.

NOTE The assembly is performed to achieve system element configuration (complete or partial) connecting the implemented system elements as prescribed in the integration strategy, using the defined assembly procedures, interface control descriptions, and the related integration enabling systems.

1. Perform check of the interfaces, selected functions, and critical quality characteristics.

NOTE This is performed to help ensure the operation of the interfaces (external and internal), functions, and quality characteristics. The interfaces are checked using the Verification process against the interface requirements.

c) **Manage results of integration.** This activity consists of the following tasks:

1. Record integration results and any anomalies encountered.

NOTE This includes anomalies due to the integration strategy, the integration enabling systems, execution of the integration or incorrect system or element definition. Where inconsistencies exist at the interface between the system, its specified operational environment and any systems that enable the utilization stage, the deviations lead to corrective actions or requirement changes. The Project Assessment and Control process is used to analyze the data to identify the root cause, enable corrective or improvement actions, and to record lessons learned.

1. Maintain traceability of the integrated system elements.

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NOTE Bi-directional traceability is maintained between the integrated system elements and the integration strategy, system architecture, design, and system requirements including interface requirements and definitions that are necessary for integration

1. Provide key information items that have been selected for baselines.

NOTE The Configuration Management process is used to establish and maintain configuration items and baselines. This process (Integration) identifies candidates for the baseline, and then provides the information items to CM. For this process, the integration strategy is a typical information item that is baselined.

**6.4.9** **Verification process**

**6.4.9.1** **Purpose**

The purpose of the Verification process is to provide objective evidence that a system or system element fulfils its specified requirements and characteristics.

The Verification process identifies the anomalies (errors, defects, or faults) in any information item (e.g., system requirements or architecture description), implemented system elements, or life cycle processes using appropriate methods, techniques, standards or rules. This process provides the necessary information to determine resolution of identified anomalies.

NOTE The Verification process determines that the "product is built right". The Validation process determines that the "right product is built".

**6.4.9.2 Outcomes**

As a result of the successful implementation of the Verification process:

1. Constraints of verification that influence the requirements, architecture, or design are identified.
2. Any enabling systems or services needed for verification are available.
3. The system or system element is verified.
4. Data providing information for corrective actions is reported.
5. Objective evidence that the realized system fulfils the requirements, architecture and design is provided.
6. Verification results and anomalies are identified.
7. Traceability of the verified system elements is established.

**6.4.9.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Verification process.

a) **Prepare for verification.** This activity consists of the following tasks:

NOTE This strategy generally focuses on minimizing cost and schedule, and/or risk, providing a balanced approach for confirming that the system or system element has been “built right”.

1. Identify the verification scope and corresponding verification actions.

NOTE Scope includes requirements, architecture and design characteristics or other properties to be verified. For each verification action, the strategy describes the system element or artifact to be verified (the actual system, or a model, a mock-up, a prototype, a procedure, a plan or other document), and the expected result, such as from its performance or conformance. Design characteristics include security implications of the design in the context of the planned operational environment and the achievement of critical quality characteristics.

1. Identify the constraints that potentially limit the feasibility of verification actions.

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NOTE Constraints include technical feasibility, cost, time, availability of verification enablers or qualified personnel, contractual constraints, and characteristics such as criticality of the mission.

1. Select appropriate verification methods or techniques and associated criteria for every verification action.

NOTE Verification methods or techniques include: inspection (including peer review), analysis (including modeling, simulation, and analogy/similarity), demonstration, or testing. The selection of verification methods or techniques are made according to the type of system, the objectives of the project, and the acceptable risks. Selected methods are coordinated with relevant stakeholders to help ensure the verification approach is acceptable.

1. Define the verification strategy.

NOTE 1 The definition includes trading off what will be verified (scope) against the constraints or limits, and deduces what verification actions to use. Verification actions that are candidates for deletion are evaluated for the risks their withdrawal imposes. The prioritized verification strategy encompasses the most appropriate verification method or technique for every verification action and the necessary verification enabling systems (simulators, test-benches, qualified personnel, location, facilities, etc.) according to selected verification methods or techniques.

NOTE 2 The verification strategy and schedule are updated according to the progress of the project; in particular planned verification actions are redefined or rescheduled when unexpected events or system evolutions occur.

1. Identify system constraints from the verification strategy to be incorporated in the system requirements, architecture, or design.

NOTE This includes practical limitations of accuracy, uncertainty, repeatability that are imposed by the verification enablers, the associated measurement methods, the need for system integration, and the availability, accessibility and interconnection with enablers.

1. Identify and plan for the necessary enabling systems or services needed to support verification.

NOTE Verification enabling systems include verification equipment, simulators, test automation tools, facilities, etc.

1. Obtain or acquire access to the enabling systems or services to be used to support verification.

NOTE The acquisition of the enabling systems can be done through various ways such as rental, procurement, development, reuse, subcontracting; usually the acquisition of the complete set of enablers is a mix of these ways. The Validation process is used to objectively confirm that the verification enabling system achieves its intended use for its enabling functions.

b) **Perform verification.** This activity consists of the following tasks:

1. Define the verification procedures, each supporting one or a set of verification actions.

NOTE The procedures identify the purpose of the verification with success criteria (expected results), the verification technique to be applied, the necessary enabling systems (facilities, equipment, etc.), and the environmental conditions to perform each verification procedure (resources, qualified personnel, etc.).

1. Perform the verification procedures.

NOTE Verification, in accordance with the verification strategy, occurs at the appropriate time in the schedule. Verification activities are performed at the appropriate point the system life cycle in the defined environment, with defined enabling systems and resources. The performance of a verification action consists of capturing a result from the execution of the verification procedure; comparing the obtained result with the expected result; and deducing a degree of correctness of the submitted element.

c) **Manage results of verification.** This activity consists of the following tasks:

1. Record verification results and any anomalies encountered.

NOTE 1 This includes anomalies due to the verification strategy, the verification enabling systems, execution of the verification, or incorrect system definition. The Project Assessment and Control process is used to analyze the data to identify the root cause, enable corrective or improvement actions, and to record lessons learned.

NOTE 2 The evaluation of verification results in the Project Assessment and Control Process and follow-up corrective action can vary greatly depending on the purpose of the verification. For elements of a system, this could

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imply a simple problem resolution action to address a failed system element verification followed by re-verification, or more significant actions such as major project re-direction based on a failure to attain a key milestone, e.g., failed system testing.

1. Record operational incidents and problems and track their resolution.

NOTE Performing problem resolution is handled through the Quality Assurance and Project Assessment and Control processes. Any actual changes to the requirements, architecture, design, or system elements are done within other Technical Processes.

1. Obtain stakeholder agreement that the system or system element meets the specified requirements.
2. Maintain traceability of the verified system elements.

NOTE Bi-directional traceability is maintained between the verified system elements and the verification strategy, system architecture, design, and system requirements.

1. Provide key information items that have been selected for baselines.

NOTE The Configuration Management process is used to establish and maintain configuration items and baselines. This process (Verification) identifies candidates for the baseline, and then provides the information items to CM. For this process, the verification strategy is a typical information item that is baselined.

**6.4.10 Transition process**

**6.4.10.1** **Purpose**

The purpose of the Transition process is to establish a capability for a system to provide services specified by stakeholder requirements in the operational environment.

This process moves the system in an orderly, planned manner into the operational status, such that the system is functional, operable and compatible with other operational systems. It installs a verified system,

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| together-- | with relevant enabling systems, e.g., planning system, support system, operator training system, user |
| NOTE-`-`,,`,,,`,``,,,`,`,``,``,,,,,,` | In the case of system upgrades, the transition activities need to be accomplished with minimal disruption to |

training system, as defined in agreements. This process is used at each level in the system structure and in each stage to complete the criteria established for exiting the stage. It includes preparing applicable storage, handling, and shipping enabling systems.

ongoing `,,`,,`,`,,` operations.

**6.4.10.2** --- **Outcomes**

As a result of the successful implementation of the Transition process:

1. Transition constraints that influence system requirements, architecture, or design are identified.
2. Any enabling systems or services needed for transition are available.
3. The site is prepared.
4. The system installed in its operational location is capable of delivering its specified functions.
5. Operators, users and other stakeholders necessary to the system utilization and support are trained.
6. Transition results and anomalies are identified.
7. The installed system is activated and ready for operation.
8. Traceability of the transitioned elements is established.

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**6.4.10.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Transition process.

a) **Prepare for the transition.** This activity consists of the following tasks:

1. Define a transition strategy.

NOTE The transition strategy includes all activities from site delivery and installation through deployment and commissioning of the system in accordance with agreements using appropriate mechanisms to help ensure system integrity is maintained. The strategy involves all the stakeholders, including human operators. The strategy includes roles and responsibilities, facilities considerations, shipping and receiving, contingency back out plans, training, installation acceptance demonstration tasks, operational readiness reviews, operations commencement, transition success criteria, and integration with other plans. Commissioning of the system is considered along with the decommissioning of the old system, when one exists. In this case, the Transition and Disposal processes are used concurrently.

1. Identify and define any facility or site changes needed.

NOTE This includes changes needed for installation or use.

1. Identify and arrange training of operators, users, and other stakeholders necessary for system utilization and support.
2. Identify system constraints from transition to be incorporated in the system requirements, architecture or design.
3. Identify and plan for the necessary enabling systems or services needed to support transition.

NOTE This includes identification of requirements and interfaces for the enabling systems.

1. Obtain or acquire access to the enabling systems or services to be used.

NOTE The Validation process is used to objectively confirm that the transition enabling system achieves its intended use for its enabling functions.

* 1. Identify and arrange shipping and receiving of system elements and enabling systems.

1. **Perform the transition.** This activity consists of the following tasks:
   1. Prepare the site of operation in accordance with installation requirements.

NOTE Site preparation is conducted in accordance with applicable health, safety, security and environmental regulations.

1. Deliver the system for installation at the correct location and time.

NOTE It is sometimes necessary to account for intermediate storage prior to delivery.

1. Install the system in its operational location and interface to its environment.

NOTE The system installation includes configuring it with required operational data, taking into account changes to the operating environment or business process changes. Data migration may need to be considered.

1. Demonstrate proper installation of the system.

NOTE Acceptance tests defined in the agreement to deliver generally demonstrate satisfactory installation. Where the exact location or environment of operation is not available, a representative example is selected. Specific attention is given to the physical interfaces.

1. Provide training of the operators, users, and other stakeholders necessary for system utilization and support.
2. Perform activation and check-out of the system.

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NOTE 1 This task takes all steps needed to activate the system to an operational state, including power-up, instrument checks, assessment of environmental conditions, and other readiness evaluations, in accordance with operational procedures, organizational policies, and regulations. This task also interacts with the Validation process to objectively confirm that the system fulfills the stakeholder requirements in the operational environment.

NOTE 2 This task includes integrity checks and conformance with technical standards. Anti-counterfeit, system and software assurance, and interoperability elements are usually considered when identifying and defining checkpoints.

1. Demonstrate the installed system is capable of delivering its required functions.

NOTE 1 Acceptance tests, as specified in agreements, can define the criteria that demonstrate that the system or system element possesses the capability to deliver the required functions and services when installed in its operational location and staffed by operators. Specific attention is given to the key functions and logical interfaces.

NOTE 2 This is an operational readiness task that examines readiness of functional capability for an operational state. The Validation process evaluates whether the system meets the stakeholder needs.

1. Demonstrate the functions provided by the system are sustainable by the enabling systems.

NOTE This is a operational readiness task that examines readiness of enabling systems for an operational state.

1. Review the system for operational readiness.

NOTE This includes the results functional demonstration, validation activities, and sustainment demonstration.

1. Commission the system for operations.

NOTE This includes providing support to the users and operators during the operations commencement (commissioning) of the system.

c) **Manage results of transition.** This activity consists of the following tasks:

1. Record transition results and any anomalies encountered.

NOTE This includes anomalies due to the transition strategy, the transition enabling systems, execution of the transition or incorrect system definition. Where inconsistencies exist at the interface between the system, its specified operational environment and any systems that enable the utilization stage, the deviations are resolved through corrective actions or changes to the requirements. The Project Assessment and Control process is used to analyze the data to identify the root cause, enable corrective or improvement actions, and to record lessons learned.

1. Record operational incidents and problems and track their resolution.

NOTE Performing problem resolution is handled through the Quality Assurance and Project Assessment and Control processes. Any actual changes to the requirements, architecture, design, or system elements are done within other Technical Processes.

1. Maintain traceability of the transitioned system elements.

NOTE Bi-directional traceability is maintained between the transitioned system elements and the transition strategy, system architecture, design, and system requirements.

1. Provide key information items that have been selected for baselines.

NOTE The Configuration Management process is used to establish and maintain configuration items and baselines. This process (Transition) identifies candidates for the baseline, and then provides the information items to CM. For this process, the transition strategy is a typical information item that is baselined.

**6.4.11 Validation process**

**6.4.11.1** **Purpose**

The purpose of the Validation process is to provide objective evidence that the system, when in use, fulfills its business or mission objectives and stakeholder requirements, achieving its intended use in its intended operational environment.

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The objective of validating a system or system element is to acquire confidence in its ability to achieve its intended mission, or use, under specific operational conditions. Validation is ratified by stakeholders. This process provides the necessary information so that identified anomalies can be resolved by the appropriate technical process where the anomaly was created.

NOTE 1 The validation process determines that the "right product is built". The verification process determines that the "product is built right".

NOTE 2 Validation is also applicable to the engineering artifacts (viewed as system elements) produced in the definition and realization of the system.

**6.4.11.2 Outcomes**

As a result of the successful implementation of the Validation process:

1. Validation criteria for stakeholder requirements are defined.
2. The availability of services required by stakeholders is confirmed.
3. Constraints of validation that influence the requirements, architecture, or design are identified.
4. The system or system element is validated.
5. Any enabling systems or services needed for validation are available.
6. Validation results and anomalies are identified.
7. Objective evidence that the realized system or system element satisfies stakeholder needs is provided.
8. Traceability of the validated system elements is established.

**6.4.11.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Validation process.

a) **Prepare for validation.** This activity consists of the following tasks:

1. Identify the validation scope and corresponding validation actions.

NOTE 1 Scope includes stakeholder requirements to be evaluated. For each validation action, the strategy describes the stakeholder needs and requirements for validation, the system or system element on which validation is performed, and the expected result from its performance. The scope depends on what is appropriate for the systems life cycle stage; it can be the system-of-interest or any system element or engineering artifact, such as a concept description or document, an operational scenario, a model, a mock-up, or prototype. The scope also includes evaluating that the product or service is predictable in its intended environment and does not enable any unintended uses that can negatively impact the intended use of the system.

NOTE 2 The supplier, the acquirer, or an agent of the acquirer participates in or performs validation. The responsibility is generally designated in the agreement.

1. Identify the constraints that potentially limit the feasibility of validation actions.

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NOTE Constraints include technical feasibility, cost, time, availability of validation enablers or qualified personnel, contractual constraints, and characteristics such as criticality of the mission.

1. Select appropriate validation methods or techniques and associated criteria for each validation action.

NOTE 1 Validation methods or techniques include: inspection, analysis, analogy/similarity, demonstration, simulation, peer-review, testing or certification. The selection of validation methods or techniques is made according to the type and purpose of the system, the objectives of the project, regulatory or legal requirements, and the acceptable risks of a validation action.

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NOTE 2 Where appropriate, validation steps or states are defined (e.g., in-house validation, on-site validation, operational validation) that progressively build confidence in conformance of the delivered system, then the installed system, then the in-service system, and assist diagnosis of any encountered discrepancies. Appropriate validation techniques needed to perform the validation actions are selected, as are defined in the purpose, conditions and conformance criteria for each validation step.

1. Define the validation strategy.

NOTE 1 The definition includes the trade-off analysis of what will be validated (scope) against the constraints or limits, and deduce what validation actions to keep. Validation actions that are candidates for deletion are evaluated for the risks their withdrawal imposes. The prioritized validation strategy is obtained defining concurrently: the most appropriate validation technique for every validation action; the necessary validation enablers (simulators, test-benches, qualified personnel, location, facilities, etc.) according to selected validation techniques.

NOTE 2 The validation strategy and schedule are updated according to the progress of the project; in particular planned validation actions are redefined or rescheduled when unexpected events or system evolutions occur.

NOTE 3 This strategy generally focuses on minimizing cost and schedule, and/or risk.

1. Identify system constraints from the validation strategy to be incorporated in the stakeholder requirements.

NOTE This includes practical limitations of accuracy, uncertainty, repeatability that are imposed by the validation enablers, the associated measurement methods, and the availability, accessibility and interconnection with enablers.

1. Identify and plan for the necessary enabling systems or services needed to support validation.

NOTE This includes identification of requirements and interfaces for enabling systems. Validation enabling systems include validation equipment, simulators, test automation tools, facilities, etc.

1. Obtain or acquire access to the enabling systems or services to be used to support validation.

NOTE There are various ways to obtain access to enabling systems such as rental, procurement, development, reuse, subcontracting. Usually access to the complete set of enablers is a mix of these ways. The Validation process is also used to objectively confirm that the validation enabling system achieves its intended use for its enabling functions.

b) **Perform validation.** This activity consists of the following tasks:

1. Define the validation procedures, each supporting one or a set of validation actions.

NOTE This includes the identification of the expected results, the validation technique to be applied, the corresponding validation enablers (facilities, equipment, etc.), and the environment conditions to perform the validation procedure (resources, qualified personnel, etc.).

1. Perform the validation procedures in the defined environment.

NOTE Validation activities are performed at the appropriate point the system life cycle, in the defined environment (as close as possible of the operational environment, or representative of it), with defined enablers and resources. The performance of a validation action consists of capturing a result from the execution of the validation procedure; comparing the obtained result with the expected result; deducing a degree of compliance of the element; and deciding about the acceptability of compliance if possible uncertainty remains.

* 1. Review validation results to confirm that the services of the system that are required by stakeholders are available.

1. **Manage results of validation.** This activity consists of the following tasks:
   1. Record validation results and any anomalies encountered.

NOTE This includes anomalies due to the validation strategy, the validation enabling systems, execution of the validation, or incorrect system definition. The Project Assessment and Control process is used to analyze the data to identify the root cause, enable corrective or improvement actions, and to record lessons learned.

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1. Record operational incidents and problems and track their resolution.

NOTE Performing problem resolution is handled through the Quality Assurance and Project Assessment and Control processes. Any actual changes to the requirements, architecture, design, or system elements are done within other Technical Processes.

1. Obtain stakeholder agreement that the system or system element meets the stakeholder needs.
2. Maintain traceability of the validated system elements.

NOTE Bi-directional traceability is maintained between the validated system elements and the validation strategy, mission/business analysis, life cycle concepts, stakeholder requirements, system architecture, design, and system requirements.

1. Provide key information items that have been selected for baselines.

NOTE The Configuration Management process is used to establish and maintain configuration items and baselines. This process (Validation) identifies candidates for the baseline, and then provides the information items to CM. For this process, the validation strategy is a typical information item that is baselined.

**6.4.12 Operation process**

**6.4.12.1** **Purpose**

The purpose of the Operation process is to use the system to deliver its services.

This process establishes requirements for and assigns personnel to operate the system, and monitors the services and operator-system performance. In order to sustain services it identifies and analyzes operational anomalies in relation to agreements, stakeholder requirements and organizational constraints.

NOTE ISO/IEC 20000-1:2011 (IEEE Std 20000-1:2013), provides requirements for establishing a service management system, which supports the Operation process to achieve its purpose.

**6.4.12.2 Outcomes**

As a result of the successful implementation of the Operation process:

1. Operation constraints that influence system requirements, architecture, or design are identified.
2. Any enabling systems, services, and material needed for operation are available.
3. Trained, qualified operators are available.
4. System services that meet stakeholder requirements are delivered.
5. System performance during operation is monitored.
6. Support to the customer is provided.

**6.4.12.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Operation process.

a) **Prepare for operation.** This activity consists of the following tasks:

1. Define an operation strategy.

NOTE

operation.

This defines approaches, schedules, resources, and specific considerations required to perform system

It often includes:

1. The availability of services as they are introduced, routinely operated and withdrawn from service. It can include co-ordination with pre-existing, concurrent or continuing services delivered by other systems that provide identical or similar services.

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* 1. The staffing strategy and schedules for operators.
  2. The release and re-acceptance criteria and schedules of the system to permit modifications that sustain existing or enhanced services.
  3. The approach to implement the operational modes in the Operational Concept, including normal operations and envisioned types of contingency operations.
  4. Measures for operation that will provide insight into performance levels.
  5. The operational and occupational safety strategy for operators and others using or in contact with the system during operation, accounting for any safety regulations.
  6. The environmental protection and sustainability strategy for operating the system.
  7. Monitoring procedures for changes in threats and the results of operational monitoring activities.

1. Identify system constraints from operation to be incorporated in the system requirements, architecture, or design.
2. Identify and plan for the necessary enabling systems or services needed to support operation.

NOTE This includes identification of requirements and interfaces for the enabling systems.

1. Obtain or acquire access to the enabling systems or services to be used.

NOTE The Validation process is used to objectively confirm that the operation enabling system achieves its intended use for its enabling functions.

1. Identify or define training and qualification requirements for personnel needed for system operation.
2. Assign trained, qualified personnel to be operators.

NOTE The training and qualification includes awareness of the system in its operational environment and a defined programmed of familiarization, with appropriate failure detection and isolation instruction. Operator knowledge, skill and experience requirements guide the personnel selection criteria, and where relevant, their authorization to operate is confirmed. The scope of qualification depends on the system-of-interest and its environment. For example, in some environments regulatory requirements include certification of operators, whereas in others there is no certification requirement. A training mode of the operational system sometimes impacts service availability.

b) **Perform operation.** This activity consists of the following tasks:

1. Use the system in its intended operational environment.

NOTE The Operation Strategy guides the system usage. Where agreed, continuous service capacity and quality is maintained when the system replaces an existing system that is being retired. During a specified period of changeover or concurrent operation, the transfer of services is managed so that continuing conformance to persistent stakeholder needs is achieved.

1. Apply materials and other resources, as required, to operate the system and sustain its services.

NOTE This includes energy sources for hardware and provisions for operators.

1. Monitor system operation.

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| NOTE 1 | This includes: |  |
| i) | Managing adherence to the operation strategy. |  |
| ii) Assuring that the system is operated in a safe manner and compliant with legislated guidelines concerning | | |
| -- | occupational safety and environmental protection. |  |
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1. Using the measures defined in the strategy and analyzing them to confirm that service performance is within acceptable parameters.

NOTE 2 Monitoring the system includes reviewing that the performance is within established thresholds, periodic instrument readings are acceptable, and service and response times are acceptable. Operator feedback and suggestions are useful input for improving system operational performance.

NOTE 3 Cost of operation is also monitored against objectives and constraints, and to identify potential improvements.

1. Identify and record when system service performance is not within acceptable parameters.

NOTE The system sometimes exhibits unacceptable performance when system elements implemented in hardware have exceeded their useful life or the system’s operational environment affects the operating and maintenance personnel (including staff turnover, operator stress and fatigue).

1. Perform system contingency operations, if necessary.

NOTE This includes operating the system in a degraded mode, performing back-out and restore operation, system shutdown, implementation of work-around procedures to restore operation, or other modes for special conditions. If needed, the operator performs steps necessary to enter into contingency operations and possibly power down the system. Contingency operations are performed in accordance with pre-established procedures for such an event. Often these procedures are accompanied by a continuity plan.

c) **Manage results of operation.** This activity consists of the following tasks:

1. Record results of operation and any anomalies encountered.

NOTE This includes anomalies due to the operation strategy, the operation enabling systems, execution of the operation, or incorrect system definition. The Project Assessment and Control process is used to analyze the data to identify the root cause, enable corrective or improvement actions, and to record lessons learned.

1. Record operational incidents and problems and track their resolution.

NOTE 1 Performing problem resolution is handled through the Quality Assurance and Project Assessment and Control processes. Any actual changes to the requirements, architecture, design, or system elements are done within other Technical Processes.

NOTE 2 If an incident is experienced during operation, the operator records the incident and performs actions prescribed in validated operating procedures to restore normal operations.

1. Maintain traceability of the Operations elements.

NOTE Bi-directional traceability is maintained between the Operations elements and the business or mission needs, operational concept, concept of operations, and stakeholder requirements.

1. Provide key information items that have been selected for baselines.

NOTE The Configuration Management process is used to establish and maintain configuration items and baselines. This process (Operation) identifies candidates for the baseline, and then provides the information items to CM.

d) **Support the customer.** This activity consists of the following task:

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| --- | --- | --- | --- | --- |
|  | 1) | Provide assistance and consultation to the customers as requested. | |  |
|  | NOTE | Assistance and consultation includes the providing of or providing recommended sources for training, | | |
|  | documentation, vulnerability resolution, anti-counterfeit reporting, and other support services supporting effective use | | | |
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|  | 2) | Record and monitor requests and subsequent actions for support. | | --`,,`,,,`,``,,,`,`,``,``,,,,,,` |
|  | 3) | Determine the degree to which delivered system services satisfy the needs of the customers. | |
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NOTE The results are analyzed and required action to restore or amend system services in order to provide continued customer satisfaction is identified. Wherever possible the benefit of such action is agreed with stakeholders or their representatives. The customer satisfaction data also serves as an input to the Quality Management process.

**6.4.13 Maintenance process**

**6.4.13.1** **Purpose**

The purpose of the Maintenance process is to sustain the capability of the system to provide a service.

This process monitors the system’s capability to deliver services, records incidents for analysis, takes corrective, adaptive, perfective and preventive actions and confirms restored capability.

**6.4.13.2 Outcomes**

As a result of the successful implementation of the Maintenance process:

a) Maintenance constraints that influence system requirements, architecture, or design are identified.

b) Any enabling systems or services needed for maintenance are available.

c) Replacement, repaired, or revised system elements are made available.

d) The need for changes to address corrective, perfective, or adaptive maintenance is reported.

e) Failure -- and lifetime data, including associated costs, is determined.

**6.4.13.3** `,,`,,,`,``,,,`,`,``,``,,,,,,` **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies-and procedures with respect to the Maintenance process.

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a) **Prepare** --- **for maintenance.** This activity consists of the following tasks:

1. Define a maintenance strategy.

NOTE 1 The maintenance strategy, also known as the maintenance concept, defines the approaches, schedules, resources, and specific considerations required to perform corrective and preventive maintenance in conformance with operational availability requirements. It generally includes:

1. The corrective and preventive maintenance strategy to sustain service in the operational environment in order to achieve customer satisfaction.
2. The scheduled preventive maintenance actions that reduce the likelihood of system failure without undue loss of services or impact on normal operations, (e.g., suspension or restriction of the services).
3. The logistics strategy throughout the life cycle, including acquisition logistics (helps ensure supportability implications are considered early during the Development stage) and operations logistics (helps ensure that the necessary material and resources, in the right quantity and quality, are available at the right place and time throughout the Utilization and Support Stages).
4. The number and type of replacement system elements to be stored, their storage locations and conditions, their anticipated replacement rate, and their storage life and renewal frequency.
5. Approach to assure that counterfeit system elements are not introduced into the system.
6. The skill and personnel levels required to effect repairs, replacements, and restoration accounting for maintenance staff requirements and any relevant legislation regarding health and safety, security and the environment.
7. Measures for maintenance that will provide insight into performance levels, effectiveness, and efficiency.

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NOTE 2 [Reliability Centered Maintenance (RCM)](#page1) is a cost-effective maintenance strategy to address dominant causes of equipment failures (supported by [Failure Modes, Effects, and Criticality Analysis {FMECA}](#page1) and Fault Tree Analysis). It provides a systematic approach to defining a routine maintenance program composed of cost-effective tasks that preserve important functions. SAE JA1011:2009, *Evaluation Criteria for Reliability-Centered Maintenance* *(RCM) Processes*, provides detailed information. Condition Based Maintenance (CBM/CBM+) is a strategy to improvesystem reliability by reducing the amount of time the system is unavailable while conducting routine or corrective maintenance.

NOTE 3 In most cases, the extension of capability, mid-life upgrade, or evolution of legacy systems becomes a new system development project that will apply the set of processes within an appropriate life cycle as applicable.

1. Identify system constraints from maintenance to be incorporated in the system requirements, architecture, or design.

NOTE These often result from the need to 1) re-use existing maintenance enabling systems; 2) re-use existing holdings of replaceable system element and accommodate re-supply limitations; 3) conduct maintenance in specific locations or environments.

1. Identify trades such that the system and associated maintenance and logistics actions results in a solution that is affordable, operable, supportable, and sustainable.

NOTE The System Analysis and Decision Management processes are used to perform the assessments and trade decisions.

1. Identify and plan for the necessary enabling systems or services needed to support maintenance.

NOTE This includes identification of requirements and interfaces for the enabling systems.

1. Obtain or acquire access to the enabling systems or services to be used.

NOTE The Validation process is used to objectively confirm that the maintenance enabling system achieves its intended use for its enabling functions.

1. **Perform maintenance.** This activity consists of the following tasks:
   1. Review incident and problem reports to identify future corrective, adaptive, perfective and preventive maintenance needs.
   2. Record maintenance incidents and problems and track their resolution.

NOTE 1 If an incident is experienced during maintenance, the maintenance staff records the incident and performs actions prescribed in validated maintenance procedures.

NOTE 2 Performing maintenance problem identification and resolution is handled through the Quality Assurance and Project Assessment and Control processes.

1. Implement the procedures for correction of random faults or scheduled replacement of system elements.

NOTE For random system failures, the fault is isolated down to the planned level of system element replacement, repair, revision, or reconfiguration. Then the corrective actions for the system element are performed and correct system performance is verified. Actions are recorded in order to estimate the useful life of degradable system elements.

1. Upon encountering random faults that cause a system failure, deploy actions to restore the system to operational status.

NOTE Restoration to full operational status may not be possible until the cause of the fault is corrected. In that case, the system is restored to a degraded mode consistent with the contingency planning.

1. Perform preventive maintenance by replacing or servicing system elements prior to failure, according to planned schedules and maintenance procedures.
2. Perform failure identification actions when a non-compliance has occurred in the system.

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1. Identify when adaptive or perfective maintenance is required.

NOTE Adaptive and perfective maintenance actions usually involve change to the system requirements, architecture or design. It may be necessary to establish a new project to modify the existing system. If so, the Portfolio Management process may be the starting point to initiate the work from the Development stage.

c) **Perform logistics support.** This activity consists of the following tasks:

1. Perform acquisition logistics.

NOTE Acquisition Logistics considerations are included in the agreement resulting from the Agreement processes. Supportability implications are also considered during the Development stage. This includes performing analysis to determine whether it is more cost effective to influence the initial design of the system or to plan for spare parts and repairs during utilization. These decisions are often constrained by availability requirements and impact the supply chain management. Acquisition logistics considers the supportability needs of the system concurrently with the definition of the system requirements.

1. Perform operational logistics.

NOTE Operational logistics is the concurrent tuning of both the SOI and enabling systems throughout the operational life to help ensure effective and efficient delivery of system functions. It also includes taking the steps necessary to help ensure that the necessary material and resources, in the right quantity and quality, are available at the right place and time.

1. Implement any packaging, handling, storage and transportation needed during the life cycle.

NOTE This includes packaging, handling, storage and transportation for the system, system elements, and the required replacement system elements. This is often required to support the objectives of the Integration and Transition processes.

1. Confirm that logistics actions satisfy the required replenishment levels so that stored system elements meet repair rates and planned schedules.

NOTE Monitor the quality and availability of spares, their transportation and their continued integrity during storage. Acquire, train and accredit, as necessary, personnel to maintain operator numbers and skills.

1. Confirm that logistics actions include supportability requirements that are planned, resourced, and implemented.

NOTE The logistics actions enable the system to achieve operational readiness. The actions include staffing, supply support, support equipment, technical data needs (manuals, instructions, lists, etc.), training support, equipment/computing resource support, and facilities.

d) **Manage results of maintenance and logistics.** This activity consists of the following tasks:

1. Record maintenance and logistics results and any anomalies encountered.

NOTE This includes anomalies due to the maintenance strategy, the maintenance enabling systems, execution of the maintenance and logistics, or incorrect system definition. The Project Assessment and Control process is used to analyze the data to identify the root cause, enable corrective or improvement actions, and to record lessons learned.

1. Record operational incidents and problems and track their resolution.

NOTE Performing problem resolution is handled through the Quality Assurance and Project Assessment and Control processes. Any actual changes to the requirements, architecture, design, or system elements are done within other Technical Processes.

1. Identify and record trends of incidents, problems, and maintenance and logistics actions.

NOTE 1 This is used to inform operations and maintenance personnel, and other projects that are creating or utilizing similar system entities.

NOTE 2 Incident and problem reporting, including resulting action taken, is tracked through Incident and process Management activity of the Quality Assurance process.

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1. Maintain traceability of the Maintenance elements.

NOTE Bi-directional traceability is maintained between the maintenance actions and the system elements and life cycle artifacts.

1. Provide key information items that have been selected for baselines.

NOTE The Configuration Management process is used to establish and maintain configuration items and baselines. This process (Maintenance) identifies candidates for the baseline, and then provides the information items to CM. Examples include maintenance plans and life cycle support plans.

1. Monitor customer satisfaction with system and maintenance support.

NOTE The customer satisfaction data is used in the Quality Management process. ISO 10004:2012 contains guidelines for monitoring and measuring customer satisfaction.

**6.4.14 Disposal process**

**6.4.14.1** **Purpose**

The purpose of the Disposal process is to end the existence of a system element or system for a specified intended use, appropriately handle replaced or retired elements, and to properly attend to identified critical disposal needs (e.g., per an agreement, per organizational policy, or for environmental, legal, safety, security aspects).

This process deactivates, disassembles and removes the system or any of its system elements from the specific use. It addresses any waste products, consigning them to a final condition and returning the environment to its original or an acceptable condition. The waste products can be in-process resulting during any life cycle stage, e.g., waste materials during fabrication. This process destroys, stores or reclaims system elements and waste products in an environmentally sound manner, in accordance with legislation, agreements, organizational constraints and stakeholder requirements. Disposal includes preventing expired, non-reusable, or inadequate elements from getting back into the supply chain. Where required, it maintains records in order that the health of operators and users, and the safety of the environment, can be monitored. When part of the system will continue to be in use in a modified form, the Disposal process helps ensure the proper handling of the portion being retired.

NOTE The Disposal process is intended to be applicable throughout the life cycle of the system, including disposing prototypes during the Concept and Development stages, dealing with waste during the Production stage, and decommissioning elements from modifications during the Utilization and Support stages.

**6.4.14.2 Outcomes**

As a result of the successful implementation of the Disposal process:

1. Disposal constraints are provided as inputs to requirements, architecture, design, and implementation.
2. Any enabling systems or services needed for disposal are available.
3. The system elements or waste products are destroyed, stored, reclaimed or recycled in accordance with safety and security requirements.
4. The environment is returned to its original or an agreed state.
5. Records of disposal actions and analysis are available.

**6.4.14.3** **Activities and tasks**

The project shall implement the following activities and tasks in accordance with applicable organization policies and procedures with respect to the Disposal process.

1. **Prepare for disposal.** This activity consists of the following tasks:
   1. Define a disposal strategy for the system, to include each system element and any resulting waste products.

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NOTE This defines schedules, actions and resources that:

1. permanently terminate the system's functions and delivery of services.
2. transform the system into, or retain it in, a socially and physically acceptable state, thereby avoiding subsequent adverse effects on stakeholders, society and the environment.
3. take account of the health, safety, security and privacy applicable to disposal actions and to the long term condition of resulting physical material and information.
4. considers transition of the system for future use in modified or adapted form, including legacy migration.
5. Identify system constraints from disposal on the system requirements, architecture and design characteristics, or implementation techniques.

NOTE This includes issues of disassembly, including their associated enabling systems, access to and availability of storage locations and available skill levels.

1. Identify and plan for the necessary enabling systems or services needed to support disposal.

NOTE This includes identification of requirements and interfaces for the enabling systems.

1. Obtain or acquire access to the enabling systems or services to be used.

NOTE The Validation process is used to objectively confirm that the disposal enabling system achieves its intended use for its enabling functions.

* 1. Specify containment facilities, storage locations, inspection criteria and storage periods, if the system is to be stored.
  2. Define preventive methods to preclude disposed elements and materials that should not be repurposed, reclaimed or reused from re-entering the supply chain.

1. **Perform disposal.** This activity consists of the following tasks:
   1. Deactivate the system or system element to prepare it for removal.

NOTE Interfaces to other systems are considered, e.g., power or fuel are disconnected in accordance with disassembly instructions, and relevant health, safety, security and privacy legislation. When the System-of-Interest is being modified for technology or capability upgrades, only the impacted system elements are deactivated and removed. This can apply to a prototype of the System-of-Interest during the Concept or Development stage,

1. Remove the system, system element, or waste material from use or production for appropriate disposition and action.

NOTE The disposition includes reuse, recycling, reconditioning, overhaul, or destruction. The disposition and subsequent actions are conducted in accordance with relevant safety, security, privacy and environmental standards, directives and laws. Elements of the system that have useful life remaining, either in their current condition or following overhaul or modification, are transferred to other systems-of-interest or organizations. Where appropriate, recondition system elements to extend their useful life. Reallocate, redeploy or retire operators. When the element is expired, non-reusable, or inadequate, it is necessary to prevent the elements from getting back into the supply chain. This task includes the removal of waste material from production or other stages.

1. Withdraw impacted operating staff from the system or system element and record relevant operating knowledge.

NOTE This is conducted in accordance with relevant safety, security, privacy and environmental standards, directives and laws. Act to safeguard and secure knowledge and skills possessed by operators. Refer to knowledge management process.

1. Disassemble the system or system element into manageable elements to facilitate its removal for reuse, recycling, reconditioning, overhaul, archiving or destruction.

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1. Handle system elements and their parts that are not intended for reuse in a manner that will assure they do not get back into the supply chain.
2. Conduct destruction of the system elements, as necessary, to reduce the amount of waste treatment or to make the waste easier to handle.

NOTE This activity includes obtaining the destruction services required in order to melt, crush, incinerate, demolish, or eradicate the system or its elements as necessary.

1. **Finalize the disposal.** This activity consists of the following tasks:
   1. Confirm that no detrimental health, safety, security and environmental factors exist following disposal.
   2. Return the environment to its original state or to a state that specified by agreement.
   3. Archive information gathered through the lifetime of the system to permit audits and reviews in the event of long-term hazards to health, safety, security and the environment, and to permit future system creators and users to build a knowledge base from past experiences.

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**Annex A**

(normative)

**Tailoring Process**

**A.1 Introduction**

This Annex provides requirements for the tailoring of this International Standard.

NOTE 1 Tailoring is not a requirement for conformance to the standard. In fact, tailoring is not permitted if a claim of "full conformance" is to be made. If a claim of "tailored conformance" is made, then this process is applied to perform the tailoring.

NOTE 2 Additional guidance for tailoring can be found in the ISO/IEC/IEEE TR 24748 guides, on the application of life cycle processes.

**A.2 Tailoring process**

**A.2.1 Purpose**

The purpose of the Tailoring process is to adapt the processes of this International Standard to satisfy particular circumstances or factors that:

1. Surround an organization that is employing this International Standard in an agreement;
2. Influence a project that is required to meet an agreement in which this International Standard is referenced;
3. Reflect the needs of an organization in order to supply products or services.

**A.2.2 Outcomes**

As a result of the successful implementation of the Tailoring process:

1. Modified or new life cycle processes are defined to achieve the purposes and outcomes of a life cycle model.

**A.2.3 Activities and tasks**

If this International Standard is tailored, then the organization or project shall implement the following tasks in accordance with applicable policies and procedures with respect to the Tailoring process, as required.

1. Identify and record the circumstances that influence tailoring. These influences include, but are not limited to:
   1. stability of, and variety in, operational environments;
   2. risks, commercial or performance, to the concern of interested parties;
   3. novelty, size and complexity;
   4. starting date and duration of utilization;
   5. integrity issues such as safety, security, privacy, usability, availability;
   6. emerging technology opportunities;

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* 1. profile of budget and organizational resources available;
  2. availability of the services of enabling systems;
  3. roles, responsibilities, accountabilities and authorities in the overall life cycle of the system;
  4. the need to conform to other standards.

1. In the case of properties critical to the system, take due account of the life cycle structures recommended or mandated by standards relevant to the dimension of the criticality.
2. Obtain input from parties affected by the tailoring decisions. This includes, but may not be limited to:
   1. the system stakeholders;
   2. the interested parties to an agreement made by the organization;
   3. the contributing organizational functions.
3. Make tailoring decisions in accordance with the Decision Management process to achieve the purposes and outcomes of the selected life cycle model.

NOTE 1 Organizations establish standard life cycle models as a part of the Life Cycle Model Management process. It is sometimes appropriate for an organization to tailor processes of this International Standard in order to achieve the purposes and outcomes of the stages of a life cycle model to be established.

NOTE 2 Projects select an organizationally-established life cycle model for the project as a part of the Project Planning process. It is sometimes appropriate to tailor organizationally adopted processes to achieve the purposes and outcomes of the stages of the selected life cycle model.

NOTE 3 In cases where projects are directly applying this International Standard, it is sometimes appropriate to tailor processes of this International Standard in order to achieve the purposes and outcomes of the stages of a suitable life cycle model.

e) Select the life cycle processes that require tailoring and delete selected outcomes, activities, or tasks.

NOTE 1 Irrespective of tailoring, organizations and projects are always permitted to implement processes that achieve additional outcomes or implement additional activities and tasks beyond those required for conformance to this standard.

NOTE 2 An organization or project sometimes encounter a situation where there is the desire to modify a provision of this International Standard. Modification is to be avoided because of unanticipated consequences on other processes, outcomes, activities or tasks. If necessary, modification is performed by deleting the provision (making the appropriate claim of tailored conformance) and, with careful consideration of consequences, implementing a process that achieves additional outcomes or performs additional activities and tasks beyond those of the tailored standard.

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**Annex B**

(informative)

**Example process information items**

**B.1 Introduction**

The following table provides a possible set of information items that may be associated with each process.

NOTE See ISO/IEC/IEEE 15289 for additional guidance on Information Items.

**Agreement Processes**

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**Acquisition Process**

Request for Supply

Supplier Selection Report

Agreement

Agreement Change Management Procedure

Agreement Change Report

Supply Assessment Report

Delivery Acceptance Report

**Supply Process**

Supply Response (e.g., proposal, tender)

Agreement Change Management Procedure

Agreement Change Requests

Supply Delivery Records

**Organizational Project-Enabling Processes**

****

**Life Cycle Model Management Process**

Life Cycle Policies, Processes

Life Cycle Procedures

Life Cycle Models

Process Assessment Results

Process Improvement Report

**Infrastructure Management Process**

|  |  |  |  |
| --- | --- | --- | --- |
| Infrastructure-- | | | Requirements |
|  | |  | |
| Portfolio-`-`,,`,,,`,``,,,`,`,``,``,,,,,,` | | Analysis Report | |
| Infrastructure Elements | | | |
|  | | | |
| Infrastructure Change Requests | | | |
|  | | | |
| **Portfolio Management Process** | | | |
|  |  | | |
|  |  | | |
| Project`,,`,,`,`,,`--- | Evaluation Report | | |
| Project | Initiation Report | | |
|  |  | | |
|  |  | | |
| Project | Closure Report | | |

**Human Resource Management Process**

Required Skills Report

Skills Inventory

Skill Development Assets

Skill Development Records

Qualified Personnel

Staff Assignment Records

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**Quality Management Process**

Quality Management Policies, Objectives & Procedures

Quality Assurance Assessment Report

Corrective & Preventive Action Report

**Knowledge Management Process**

Knowledge, Skill, & Knowledge Asset Records Knowledge, Skill, & Knowledge Asset Report Knowledge, Skill, & Knowledge Management Elements

**Technical Management Processes**

****

**Project Planning Process**

Project Technical Management Plan

Project Life Cycle Model

Work Breakdown Structure

Project Schedules

Project Budgets

Project Infrastructure & Services Requirements

Project Authorization Record

**Project Assessment & Control Process**

Project Assessment Records

Measurement Analysis Results & Recommendations Project Assessment Reports Project Control Requests

Authorization to Proceed to Next Milestone

**Decision Management Process**

Decision Register

Decision Report

**Risk Management Process**

Risk Profile

Risk Action Requests

Risk Profile Reports

**Configuration Management Process**

Configuration Management Records

Configuration Baselines

CM Change / Variance Requests

Configuration Status Reports

Configuration Evaluation Reports

System Release Reports

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**Information Management Process**

Information Item Register

Information Management Reports

**Measurement Process**

Measurement Records

Measurement Information Needs Report

**Quality Assurance Process**

QA Evaluation Reports

QA Records

Incident Records

Problem Records

**Technical Processes**

****

**Business or Mission Analysis Process**

Preliminary Life cycle Concepts

Problem or Opportunity Statement

Solution Alternatives & Recommendation

**Stakeholder Needs & Requirements Definition Process**

Operational Concept

Other Life cycle Concepts

Stakeholder Needs

Stakeholder Requirements

Stakeholder Requirements Report

Critical Performance Measures

Traceability Mapping

**System Requirements Definition Process**

System Description

System Requirements

System Requirements Report

Critical Performance Measures

Traceability Mapping

**Architecture Definition Process**

Architecture Viewpoints

Architecture Views & Models

Architecture Report with rationales

Interface Definitions (initial)

Architecture Assessment Report

Traceability Mapping

**Design Definition Process**

Design Characteristics Report

Design Artifacts

Design Artifacts Report with rationales

Interface Definitions

Traceability Mapping

**System Analysis Process**

System Analysis Report

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**Implementation Process**

System Elements

Implementation Records

Implementation Report

Traceability Mapping

**Integration Process**

Integrated System Elements

Integration Records

Integration Report

Traceability Mapping

**Verification Process**

Verified System

Verification Records

Verification Report

Traceability Mapping

**Transition Process**

Prepared Site for Operations

Installed System

Transition Records

Transition Report

Traceability Mapping

**Validation Process**

Validated System

Validation Records

Validation Report

Traceability Mapping

**Operation Process**

Operation Records

Operational Problem Reports

Customer Support Records

Operation Report

**Maintenance Process**

Replacement System Elements

Maintenance Records

Maintenance Requests

Maintenance Problem Reports

Logistics Actions & Report

Maintenance Report

**Disposal Process**

Disposed Items

Disposal Records

Archive Report

**Table B.1 — Example Information Items**

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**Annex C**

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**Process reference model for assessment purposes**

**C.1 Introduction**

It is understood that some users of this International Standard may desire to assess the implemented processes in accordance with ISO/IEC 15504-2. This annex provides a Process Reference Model suitable for use in conjunction with that standard.

The Process Reference Model is composed of the processes in the body of this International Standard, including the name, statement of purpose, and statement of outcomes for each process. Clause C.3 identifies the processes in the process reference model and the clauses in which they are defined.

**C.2 Conformance with ISO/IEC 15504-2**

**C.2.1 General**

ISO/IEC 15504-2 subclause 6.2 places requirements on process reference models suitable for assessment by that standard. The following sections quote the requirements for process reference models and describe how these are met by this international standard. In each of the following subclauses the *italicized* text quotes the requirement from the text of ISO/IEC 15504-2 and the non-italicized (upright) text describes the manner in which the requirement is satisfied in this International Standard.

**C.2.2 Requirements for process reference models**

*A Process Reference Model shall contain:*

1. *A declaration of the domain of the Process Reference Model*. This is provided in Clause 1.
2. *A description, meeting the requirements of subclause 6.2.4 of this International Standard* [15504]*, of the processes within the scope of the Process Reference Model.* This is provided in Annex C.3.
3. *A description of the relationship between the Process Reference Model and its intended context of use.* This is provided by Clause 5.
4. *A description of the relationship between the processes defined within the Process Reference Model.* Thisis provided in Annex C.3 in the description of each process. For example, some process descriptions include the statement that the process contains lower-level processes.

*The Process Reference Model shall document the community of interest of the model and the actions taken to achieve consensus within that community of interest:*

1. *The relevant community of interest shall be characterized or specified.* The relevant community of interestis the users of ISO/IEC/IEEE 15288 and ISO/IEC/IEEE 12207.
2. *The extent of achievement of consensus shall be documented.* Both ISO/IEC/IEEE 15288 andISO/IEC/IEEE 12207 are international standards satisfying the consensus requirements of ISO/IEC JTC1.
3. *If no actions are taken to achieve consensus, a statement to this effect shall be documented.* (Notapplicable).

*The processes defined within a Process Reference Model shall have unique process descriptions and identification.* The process descriptions are unique. The identification is provided by unique names and by theclause numbering of this annex.

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**C.2.3 Process descriptions**

*The fundamental elements of a Process Reference Model are the descriptions of the processes within the scope of the model. The process descriptions in the Process Reference Model incorporate a statement of the purpose of the process, which describes at a high level the overall objectives of performing the process, together with the set of outcomes that demonstrates successful achievement of the process purpose. These process descriptions shall meet the following requirements:*

1. *a process shall be described in terms of its purpose and outcomes;*
2. *in any process description the set of process outcomes shall be necessary and sufficient to achieve the purpose of the process;*
3. *process descriptions shall be such that no aspects of the Measurement Framework as described in Clause 5 of [ISO/IEC 15504-2] beyond level 1 are contained or implied.*

*An outcome statement describes one of the following:*

Production of an artifact;

A significant change of state;

Meeting of specified constraints, e.g., requirements, goals, and objectives.

These requirements are met by the process descriptions in this annex. Some outcomes might be interpreted as contributing to levels of capability above level 1. However, conforming implementation of the relevant processes does not require achievement of these higher levels of capability.

**C.3 The process reference model**

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The Process Reference Model (PRM) is composed of the statement of purpose and outcomes of each of the processes included in Clause 6 of this International Standard. The PRM for the system life cycle is composed of the set of processes in Figure 4.

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**Annex D**

(informative)

**Process integration and process constructs**

**D.1 Introduction**

A harmonization project within ISO/IEC JTC 1/SC 7 — a parallel, carefully coordinated revision of ISO/IEC/IEEE 15288 and ISO/IEC/IEEE 12207, and development of the ISO/IEC/IEEE TR 24748 series of guides, which provides guidelines to both of these International Standards — is the first, large step towards an integrated set of standards describing system and software life cycles. Concepts of continual process improvement and capability assessment are now well established and recognized, and are being standardized in the ISO/IEC 15504 series of standards. The Process Reference Models in Annex C of ISO/IEC/IEEE 15288 and ISO/IEC/IEEE 12207 are intended to be used in conjunction with the ISO/IEC 15504 series of standards for capability assessment of the life cycle processes. Capability determination of processes requires that the process descriptions include a clear statement of the purpose of the process and a description of the expected outcomes. Consistent implementation of the processes is aided by having activities, tasks, and implementation notes defined. Thus, the life cycle processes in both life cycle standards have adopted common process constructs, as defined in Clause D.2, Process constructs and their usage, and is consistent with the process definition guidance contained in ISO/IEC TR 24774.

**D.2 Process constructs and their usage**

The process descriptions in this International Standard follow clearly defined rules. Firstly, they were grouped in a logical fashion. Those groupings are dictated by:

Logical relations among the processes

Responsibility for execution of the processes

This International Standard groups the activities that may be performed during the life cycle of the system into

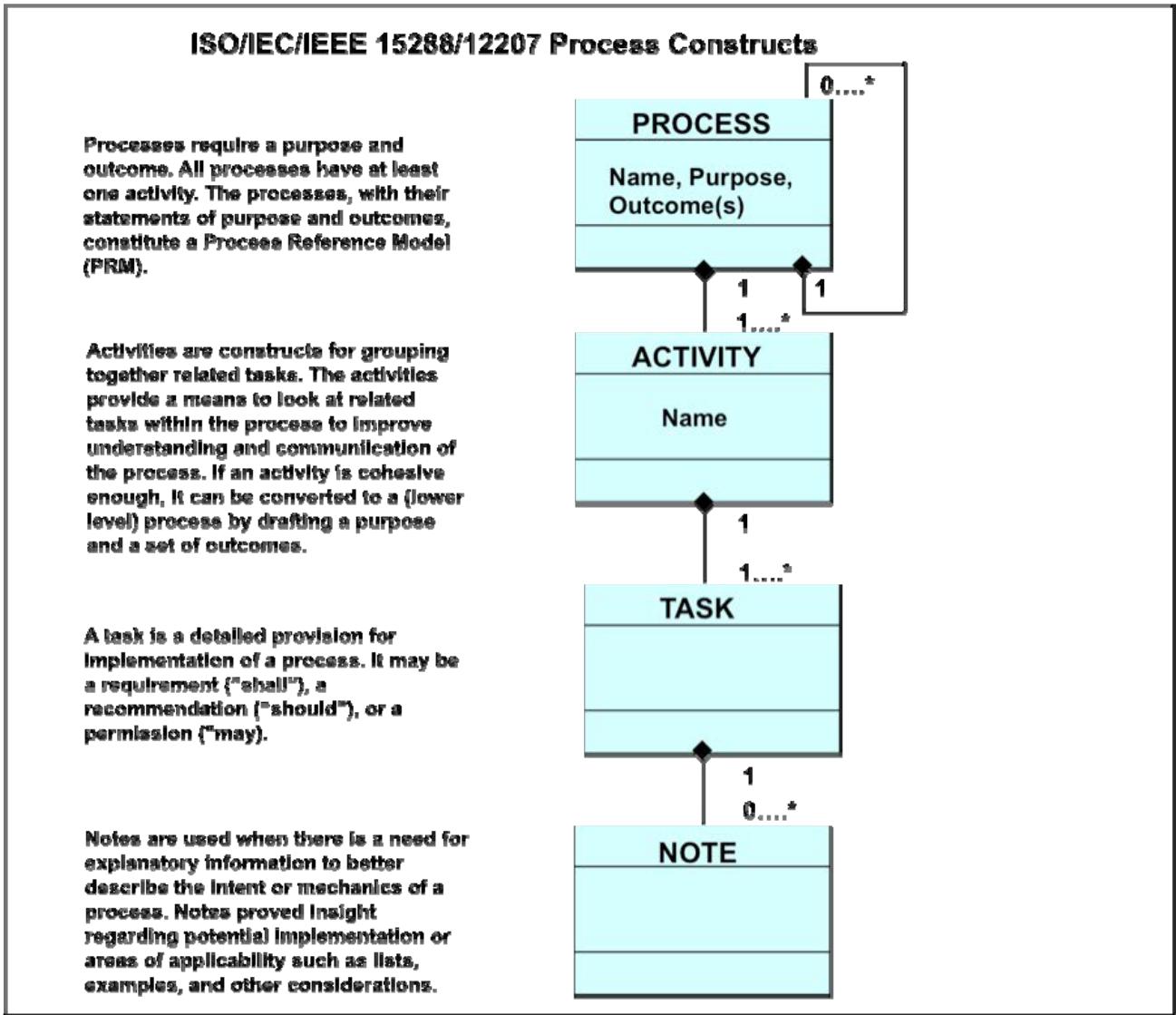
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| four | | Process Groups. The top level description of these groups can be found in subclause 5.6. Each life cycle |
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| process within those groups is described in terms of its purpose and desired outcomes and lists the activities | | |
| and tasks that need to be performed to achieve those outcomes. | | |
| a) | Agreement Processes – two processes (subclause 6.1) | |
| b) | ---`,,`,,`,`,,` |  |
| Organizational Project-Enabling Processes – six processes (subclause 6.2) | |
| c) | Technical Management Processes – eight processes (subclause 6.3) | |
| d) | Technical Processes – fourteen processes (subclause 6.4) | |

Consistent application of process description rules allows for the normalized clause numbering. Within this International Standard a subclause numbered as 6.x denotes a process group and 6.x.y denotes a process within that group. Subclauses numbered as 6.x.y.1 describe the purpose of a process, subclauses numbered 6.x.y.2 describe the outcomes of a process, and subclauses numbered as 6.x.y.3 describe the activities and tasks of a process.

Figure D.1 is a UML representation of process constructs used in this International Standard and in ISO/IEC/IEEE 12207.

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**Figure D.1 — ISO/IEC/IEEE 12207/15288 Process Constructs**

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**Annex E**

(informative)

**Process views**

**E.1 Introduction**

There are instances where those representing a particular engineering interest would like to see gathered in a single place the set of process activities that directly and succinctly address their concern. For such interests, a process view can be developed to organize processes, activities, and tasks selected from ISO/IEC/IEEE 15288 or ISO/IEC/IEEE 12207 to provide a focus to their particular concern in a manner that cuts across all or parts of the life cycle. This annex provides a process viewpoint that may be used to define process views in these instances.

**E.2 The process view concept**

There may be cases where a unified focus is needed for activities and tasks that are selected from disparate processes to provide visibility to a significant concept or thread that cuts across the processes employed across the life cycle. It is useful to advise users of the standards how to identify and define these activities for their use, even though they cannot locate a single process that addresses their specific concern.

For this purpose, the concept of a process view has been formulated. Like a process, the description of a process view includes a statement of purpose and outcomes. Unlike a process, the description of a process view does not include activities and tasks. Instead, the description includes guidance explaining how the outcomes can be achieved by employing the activities and tasks of the various processes in ISO/IEC/IEEE 15288 and ISO/IEC/IEEE 12207. Process views can be constructed using the process viewpoint template found in E.3.

**E.3 Process viewpoint**

A process view conforms to a process viewpoint. The process viewpoint provided here can be used to create process views.

The process viewpoint is defined by:

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`,,`,,,`,``,,,`,`,``,``,,,,,,` its stakeholders: users of the standard;

the concerns it frames: the processes needed to reflect a particular engineering interest.

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The ` contents of resulting process views should include:

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--- process view name;

process view purpose;

process view outcomes; and

identification and description of the processes, activities and tasks that implement the process view, and references to the sources for these processes, activities and tasks in other standards.

NOTE The requirements for documenting viewpoints are found in ISO/IEC/IEEE 42010, subclause 5.4. This description is consistent with those requirements.

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**E.4 Process view for specialty engineering**

This section provides an example of applying the process viewpoint to yield a process view for specialty engineering, intended to illustrate how a project can assemble processes, activities and tasks of ISO/IEC/IEEE 15288 to provide focused attention to the achievement of product characteristics that have been selected as being of special interest.

This example treats the cluster of interests, generally called specialty engineering, which includes but is not limited to such areas as availability, maintainability, reliability, safety, security, human factors, and usability. Within ISO/IEC/IEEE 15288, these "ilities" requirements are referred to as "critical quality characteristics". These characteristics determine how well the product meets its specified requirements in a specific area selected for focus.

NOTE This is a generalized instance of a process view that covers a broad set of functional and non-functional characteristics related to specialty engineering. It provides a broad view across the processes. If a specific critical quality characteristic has a high priority relative to other characteristics, a specific process view could be created for that characteristic, including more detailed information and requirements.

*Name:* Specialty Engineering process View

*Purpose:* The purpose of the Specialty Engineering process View is to provide objective evidence that thesystem achieves satisfactory levels of certain critical quality characteristics selected for special attention.

*Outcomes:*

1. Product critical quality characteristics are selected for special attention.
2. Requirements for the achievement of the critical quality characteristics are defined.
3. Measures for the requirements are selected and related to the desired critical quality characteristics.
4. Approaches for achieving the desired critical quality characteristics are defined and implemented.
5. The extent of achievement of the requirements is continually monitored.
6. The extent of achievement of the critical quality characteristics are specified and developed.

NOTE The outcomes permit the possibility that the desired critical quality characteristics cannot be directly measured

but instead might be argued and inferred based on other product or process characteristics that can be measured.

*Processes, Activities and Tasks:*

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This process view can be implemented using the following processes, activities, and tasks from ISO/IEC/IEEE`,,`,,,`,``,,,`,`,``,``,,,,,,` 15288:

NOTE 1 ISO/IEC 25030, Software Engineering — Software product quality requirements and evaluation (SQuaRE) —

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| Quality requirements, may be useful in specifying software product quality requirements. | -- |
|  |

NOTE 2 INCOSE Systems Engineering Handbook contains descriptions and elaboration about many of the specialty engineering areas and the associated critical quality characteristics.

1. The Business and Mission Analysis process (6.4.1) provides for the definition of the problem space and characterization of the solution space, including the relevant trade-space factors and preliminary life cycle concepts. This includes developing an understanding of the context and any key parameters, such as the critical quality characteristics (e.g., security threats, safety hazards, human interfaces, operational characteristics, and system assurance context). Relevant activities and tasks include (b)(1) and (2); (c)(1); and (d)(1).
2. The Stakeholder Needs and Requirements Definition process (6.4.2) provides for the selection and definition of characteristics, including critical quality characteristics, and associated information items. The activities and the documentation are useful in identifying, prioritizing, defining, and recording requirements

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for the critical quality characteristics. Relevant activities and tasks include (a)(1) and (2); (b)(2),(3) and (4); (c)(1) and (2); (d) all tasks; and (e)(2).

1. The System Requirements Definition process (6.4.2) provides for the specification of parameters for the critical quality characteristics and the selection of measures for tracking the achievement of these requirements with respect to the specific system to be developed. Relevant activities and tasks include (a)(1); (b) all tasks; and (c)(2).
2. The Architecture Definition process (6.4.4) provides for the identification of stakeholder concerns from an architecture perspective. These concerns often translate into expectations or constraints across the life cycle stages that relate to the critical quality characteristics, such as utilization (e.g., availability, security, effectiveness, usability), support (e.g., reparability, obsolescence management), evolution of the system and of the environment (e.g., adaptability, scalability, survivability), production (e.g., manufacturability, testability), retirement (e.g., environmental impact, transportability), etc. This process further addresses those critical quality characteristic requirements that drive the architecture decisions, including the assessment of the architecture with respect to the concerns and associated characteristics. Relevant activities and tasks include (a)(2) and (4); (b)(1); (c)(2), (3), (4), and (5); (d)(1); and (e)(2).
3. The Design Definition process (6.4.5) provides for the determination of necessary design characteristics, which includes the critical quality characteristics, such as security of design criteria for the specialty characteristics and the evaluation of alternative designs with respect to those criteria. Relevant activities and tasks include (a)(2); (b)(1), (2), (3) (4) and (6); and (c)(2).
4. The System Analysis process (6.4.6) provides for the level of analysis needed to understand the trade space with respect to the critical quality characteristics through the conduct of mathematical analysis, modeling, simulation, experimentation, and other techniques. The analysis results are input to trades made through the Decision Management process in support of other Technical processes. Relevant activities and tasks include (a) all tasks; and (b) all tasks.
5. The Implementation process (6.4.7) provides for recording the evidence that critical quality requirements have been met. Relevant activities and tasks include (b)(3).
6. The Integration process (6.4.8) provides for planning the integration, including the considerations for critical quality characteristics, and the assurance that the achievement of the characteristics is determined and recorded. Relevant activities and tasks include (a)(1); (b)(3); and (c)(1).
7. The Verification process (6.4.9), provides for the planning and execution of a strategy to perform verification, including the critical quality characteristics. The selected verification strategy may introduce design constraints that could affect the achievement of the characteristics. Relevant activities and tasks include (a)(1) and (3); (b)(1), (2); and (c)(1) and (2).
8. The Transition process (6.4.10) provides for installing the system in its operational environment. Because some specialty properties involve a trade-off between design constraints and operational constraints, attention to installation is often important. Relevant activities and tasks include (a)(4); and (b) (4), (6), and

(7).

1. The Validation process (6.4.11) provides evidence that the services provided by the system meet the stakeholders' needs, including the critical quality characteristics. Relevant activities and tasks include (a)(1) and (3); (b)(1) and (2); (c)(1) and (2).
2. The Operation process (6.4.12) provides for usage of the system. Assuring that critical quality characteristics are appropriately achieved involves monitoring the operation of the system. Relevant activities and task include (b)(3) and (4); (c)(1) and (2); and (d)(1) and (2).
3. The Maintenance process (6.4.13) sustains the capabilities of the system, helping to ensure its ongoing availability to provide its functions, including its critical quality characteristics. This includes failure analysis, maintenance tasks, and logistics tasks needed to assure continued operation of the system. Relevant activities and tasks include (b) all tasks; (c) all tasks; and (d)(1) and (2).
4. The Disposal process (6.4.14) ends the existence of a system. The inherent need to anticipate disposal may place constraints on development. In fact, these constraints may themselves be critical quality characteristics. Relevant activities and tasks include (a)(2); (b)(1) and (2) and (c)(3).

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1. The Project Assessment and Control process (6.3.2) provides for monitoring the extent of achievement of the requirements and critical quality characteristics and communicating the results to stakeholders and managers. Relevant activities and tasks include (b)(6), (7), (9) and (10).
2. The Decision Management process (6.3.3) provides assessment of alternative requirements, architecture characteristics and design characteristics against the decision criteria, including the critical quality characteristics. Results of these comparisons are ranked, via a suitable selection model,, and are then used to decide on an optimal solution. Relevant activities and tasks include (b) all tasks; and (c)(1).
3. The Risk Management process (6.3.4), in its entirety, provides for identifying, evaluating, and handling risks of the system, including those related to meeting the critical quality characteristics.
4. The Information Management process (6.3.6), in its entirety, provides for the specification, development---

and maintenance of information items for documenting and communicating the extent of achievement. It`,,`,,`,`,,` should be noted that information items used for the purpose of critical quality characteristics are-sometimes specialized in nature. Sources for the description of these information items include industry`-`,,`,,,`,``,,,`,`,``,``,,,,,,` associations, regulators, and specific standards.

1. The Measurement process (6.3.7), in its entirety, provides for defining an approach that relates measures

to the required critical quality characteristics.--

1. The Quality Assurance process (6.3.8) addresses identified anomalies (incident and problems) that relate to the achievement of critical quality characteristics.

**E.5 Process view for interface management**

This section provides an example of applying the process viewpoint to yield a process view for interface management, intended to illustrate how a project can assemble processes, activities and tasks of ISO/IEC/IEEE 15288 to provide focused attention to the achievement of product characteristics that have been selected as being of special interest.

This example treats a specific instance of a process view, called interface management, which includes but is not limited to interface definition, design, and change management. Within ISO/IEC/IEEE 15288, the tasks that comprise interface management are fully contained within the existing processes.

*Name:* Interface Management process View

*Purpose:* The purpose of the Interface Management process View is to facilitate of the identification, definition,design and management of interfaces of the system.

*Outcomes:*

1. Business or mission needs related to interfaces are identified.
2. Stakeholder needs related to interfaces are identified
3. Requirements for the interfaces are defined.
4. Interfaces between system elements are identified and defined.
5. Interfaces between the system and external systems are identified and defined.
6. The extent of realization of the interface requirements is continually monitored.
7. The extent of achievement of the interface requirements are specified and developed.

*Processes, Activities and Tasks:*

This process view can be implemented using the following processes, activities, and tasks from ISO/IEC/IEEE 15288:

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NOTE INCOSE Systems Engineering Handbook contains descriptions and elaboration about interface management.

1. The Business and Mission Analysis process (6.4.1) provides for the definition of the problem space and characterization of the solution space, including the description of the environment and context, as well as preliminary operational concepts. It often identifies external systems that must interface with the system-of-interest. Relevant activities and tasks include (b)(1) and (2); and (c)(1)
2. The Stakeholder Needs and Requirements Definition process (6.4.2) provides for the definition of operational concepts and the interactions of the system with users and the intended environment (including other systems). It often identifies external systems that must interface with the system-of-interest. Relevant activities and tasks include (c)(1) and (2); and (d)(1) and (3).
3. The System Requirements Definition process (6.4.2) provides for the definition of the interface requirements. Relevant activities and tasks include (a)(1); (b) all tasks; (c) all tasks; and (d) all tasks.
4. The Architecture Definition process (6.4.4) provides for the identification of interfaces from an architecture perspective as the architecture models evolve. This process further describes and defines the interfaces to the extent needed for the architecture description. Relevant activities and tasks include (a)(2) and (4); (c)(1) through (4); (d) all tasks; and (f)(3) through (6),
5. The Design Definition process (6.4.5) provides for the refinement and full definition of the interfaces and the creation of the necessary information items. Relevant activities and tasks include (b)(5) and (6); and (d)(1) through (3).
6. The System Analysis process (6.4.6) provides for the level of analysis needed to understand the trade space with respect to the interface requirements and definition through the conduct of mathematical analysis, modeling, simulation, experimentation, and other techniques. The analysis results are input to trades made through the Decision Management process in support of other Technical processes. Relevant activities and tasks include (a) all tasks; and (b) all tasks.
7. The Implementation process (6.4.7) provides for development of the interfaces and recording the evidence that interface requirements for an implemented system element have been met. Relevant activities and tasks include (b)(3).
8. The Integration process (6.4.8) provides for planning the integration, including the considerations for interfaces between system elements. It also includes the integration of systems or system elements and interfaces. Relevant activities and tasks include (a)(1); (b) all tasks; and (c)(1).
9. The Verification process (6.4.9), provides evidence that the services provided by the system meet the system requirements, including the interface requirement. The process provides for the planning and execution of a strategy to perform verification, including the interface requirements. The selected verification strategy may introduce interface constraints that could affect their achievement. Relevant activities and tasks include (a)(1) and (3); (b)(1), (2); and (c)(1).
10. The Transition process (6.4.10) provides for installing the system in its operational environment. This includes identifying constraints, and checking the installation and operational state of the interfaces. Relevant activities and tasks include (a)(4); and (b) (3), (4), (6), and (7).
11. The Validation process (6.4.11) provides evidence that the services provided by the system meet the stakeholders' needs, including the interface requirements. The selected validation strategy may introduce interface constraints that could affect their achievement. Relevant activities and tasks include (a)(1), (2), and (3); (b)(1) and (2); (c)(1) and (2).
12. The Operation process (6.4.12) provides for usage of the system. There also may be constraints to the interfaces for operations. Assuring that the interface requirements are appropriately achieved involves monitoring the operation of the system. Relevant activities and task include (a)(2), (b)(3) and (4); and (c)(1) and (2).
13. The Maintenance process (6.4.13) sustains the capabilities of the system, helping to ensure its ongoing availability to provide its functions, including its interfaces. This includes failure analysis, maintenance tasks, and logistics tasks needed to assure continued operation of the system. There also may be

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constraints to the interfaces for maintenance. Relevant activities and tasks include (a)(2); (b) all tasks; and (d)(1) and (2) .

1. The Disposal process (6.4.14) ends the existence of a system. It may require activities to disengage interfaces. The inherent need to anticipate disposal may place constraints on the interfaces. Relevant activities and tasks include (a)(2) and (b)(1) and (2).
2. The Project Assessment and Control process (6.3.2) provides for monitoring the extent of achievement of the requirements, including interfaces, and communicating the results to stakeholders and decision makers. Relevant activities and tasks include (b)(6), (7), (9) and (10).
3. The Decision Management process (6.3.3) provides assessing alternative requirements, architecture characteristics and design characteristics against the decision criteria, including the interfaces. Results of these comparisons are ranked, via a suitable selection model and are then used to decide on an optimal solution. Relevant activities and tasks include (b) all tasks; and (c)(1).
4. The Risk Management process (6.3.4), in its entirety, provides for identifying, evaluating, and handling risks of the system, including those related to interfaces.
5. The Information Management process (6.3.6), in its entirety, provides for the specification, development and maintenance of information items for documenting and communicating the extent of achievement.
6. The Measurement process (6.3.7), in its entirety, provides for defining an approach that relates measures to the required interface information needs, and then generating and using those measures to address the identified interface information needs.
7. The Quality Assurance process (6.3.8) addresses identified anomalies (incident and problems) that relate to the achievement of interface requirements.

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**Annex F**

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**Architecture modeling**

**F.1 Introduction**

This annex provides information related to the Architecture Definition and Design Definition Processes in this version of the standard as they relate to the Architectural Design process in the 2008 version of ISO/IEC/IEEE 15288.

Architecture and design activities in this version are split in two processes to reflect the different practices in the systems engineering community dealing with complex systems. As one example, an architecture might be followed by different designs for different systems in a product line. In this case it is important to perform these two processes in a separate manner. Furthermore, architecture is often done for other reasons than as the basis for design, such as, for example, to drive technology investments, to adjust corporate portfolio of projects, to guide a bid/no-bid decision, etc.

The architecture of a system can be understood as a set of structured architectural entities and of their relationships, such as functions, function flows, interfaces, resource flow items, information/data elements, physical components, containers, nodes, links, communication resources, etc. These architectural entities may possess characteristics such as dimensions, environmental resilience, availability, robustness, execution efficiency, mission effectiveness, etc.

**F.2 Viewpoints, views and model kinds used in architecture**

The Architectural Definition process uses a variety of models, including the example models listed in the following section. (Traditional system engineering practice classifies some of these models as “logical models” or “physical models”, but the taxonomical distinction is unnecessary in the application of this International Standard.) A variety of views are used to represent how the system architecture addresses stakeholder concerns. Views are composed of models. Refer to ISO/IEC/IEEE 42010 for definitions of architecture terms and additional detail on architecture concepts and models.

**F.3 Logical and physical models**

**F.3.1 Functional model**

A functional model of the system is a representation of a set of functions that defines the transformations of inputs into outputs performed by the system to achieve its mission or purpose. These functions are determined by how the system is expected to behave when used as intended. Consequently, every system function is associated with an interaction between the system and its environment. Functional, performance, non-functional, and constraint requirements are usually analyzed to determine functions and input-output flows. When functions are associated with system elements, the design definition process will need to determine if each system element has been sufficiently specified to build or buy it. If the system element must be further resolved in order to achieve this sufficiency then the functions associated with the system element will also need be further resolved and properly associated with the sub elements. Typically there are multiple ways to decompose the functions that contributes to the definition of multiple candidate architectures.

**F.3.2 Behavioral model**

A behavioral model is an arrangement of functions and interfaces (internal and external) that defines how the system or its elements act under conditions to sustain the operational scenarios, including the execution sequencing and concurrency, the conditions for behavioral change and the performance. A behavioral model can be described with a set of inter-related scenarios. This includes identifying the behavioral elements (modes/states, transitions, trigger events, operational scenarios, etc.) through the life cycle.

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**F.3.3 Temporal model**

A temporal model of the system is a representation expresses how the time is taken into account in the behavior the system or its elements that present levels of execution frequency of functions (strategic level, tactical level, operational monitoring level, regulation level, etc.) corresponding to levels of decision that enable humans and program logic to monitor and control the system operations. This includes identifying temporal elements (duration, frequency, response time, triggers, timeout, stop conditions, etc.) from the operational concept and system requirements.

**F.3.4 Structural model**

A structural model of the system is a representation that shows the arrangement of elements with respect to each other and where necessary shows the interfaces between elements and with external entities. Such a model enables consolidating or identifying physical interfaces between system elements in a level of the system hierarchy and between levels of the system hierarchy, as well as those with external entities to the concerned system (in its environment/context).

**F.3.5 Mass model**

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A mass model of the system is a representation showing the position of physical volumes of system elements or of their parts in the case these are geographically distributed. It could record the expected or actual mass properties to help determine such mass properties as centre of gravity and dynamic behavior of motion. It can also be used to help allocate total system mass to its elements.

**F.3.6 Layout model**

A layout model of the system is a representation of where the system elements are placed geographically against each other. In model railroading, a layout model is a diorama containing scale track for operating trains. An automobile layout describes where on the vehicle the engine and drive wheels are found.

**F.3.7 Network model**

A network model defines an arrangement of nodes and links to help understand how resources traverse from one node to another. Resources flowing in a network can be mass, energy, data, people, etc. A network model can be used to determine throughput, latency, congestion points, etc. A network model is sometimes modeled along with a protocol stack to understand how layers in a network interact vertically up and down the stack.

**F.3.8 Other model considerations**

Stakeholder life cycle concerns such as maintenance, evolution, disposal, potential changes of environment, or obsolescence management, and non-functional requirements, are addressed defining architectural characteristics such as modularity, relative independence, upgradeability, adaptation to several environments, level of effectiveness, reliability, robustness, scalability, or resistance to environmental conditions, etc.

Other necessary models could include some of these characteristics or other critical quality characteristics. For example, a reliability model could drive the functional level of the Failure Modes and Effects Analysis (FMEA or FMECA) to help deduce potential architectural mitigations to minimize operational risks (mission loss, safety or security) related to critical concerns and functions.

Determination of which models to use in system definition can be based on examination of stakeholder concerns. The models and the resulting views can be used to express how the system architecture and design addresses their concerns and to gain better understanding of their actual needs, wants and expectations.

Furthermore, models may be used in other life cycle processes besides architecture and design definition. Model-Based Systems Engineering (MBSE) is the formalized application of modeling to support system requirements, architecture, design, analysis, verification and validation activities throughout the life cycle.

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**Annex G**

(informative)

**Application of system life cycle processes to a system of systems**

**G.1 Introduction**

A system of systems (SoS) is a system-of-interest (SOI) whose elements are themselves systems. A SoS brings together a set of systems for a task that none of the systems can accomplish on its own. Each constituent system keeps its own management, goals, and resources while coordinating within the SoS and adapting to meet SoS goals. In the context of terminology discussed in subclause 5.2.3 (as shown in Figure 3), the --composite set of systems including the original SOI, enabling systems and interacting systems, together

constitute`,,`,,,`,``,,,`,`,``,``,,,,,,` an SoS. Where there are concerns that affect the composite set, the system of systems becomes the SOI, which is considered to satisfy some business or mission objective that cannot be satisfied by the

individual constituent systems, or to understand emergent behavior of the combination.

This - annex addresses the application of system life cycle processes to such SoS. It describes general

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characteristics, `,,`,,`,`,,` the common types of SoS, and the implications throughout the life cycle.

**G.2** --- **SoS characteristics and types**

SoS are characterized by managerial and operational independence of the constituent systems, which in many cases were developed and continue to support originally identified users concurrently with users of the SoS. In other contexts, each constituent system itself is a SOI; its existence often predates the SoS, while its characteristics were originally engineered to meet the needs of their initial users. As constituents of the SoS, their consideration is expanded to encompass the larger needs of the SoS. This implies added complexity particularly when the systems continue to evolve independently of the SoS. The constituent systems also typically retain their original stakeholders and governance mechanisms, which limits alternatives to address the needs of the SoS.

SoS have been characterized into four types based on the governance relationships between the constituent systems and the SoS (Figure G.1). The strongest governance relations apply to directed system of systems, where the SoS organization has authority over the constituent systems despite the fact that the constituent systems may not have originally been engineered to support the SoS. Somewhat less control is afforded for acknowledged SoS, where allocated authority between the constituent systems and the systems of systems has an impact on application of some of the systems engineering processes. In collaborative SoS, which lack system of systems authorities, application of systems engineering depends on cooperation among the constituent systems. Virtual systems of systems are largely self organizing and offer much more limited opportunity for systems engineering of the SoS.

Emergence is a key characteristic of SoS – the unanticipated effects at the systems of systems level attributed to the complex interaction dynamics of the constituent systems. In SoS, constituent systems are intentionally considered in their combination, so as to obtain and analyze outcomes not possible to obtain with the systems alone. The complexity of the constituent systems and the fact they may have been designed without regard to their role in the SoS, can result in new, unexpected behaviors. Identifying and addressing unanticipated emergent results is a particular challenge in engineering SoS.

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|  | • Lack a central management authority |
| **Virtual** | • Lack of centrally agreed upon purpose |
| • Emerging behaviors that rely upon relatively invisible |
|  |
|  | mechanisms to maintain it |
|  | • Component systems interact voluntarily to fulfill agreed upon |
| **Collaborative** | purposes |
| • Collectively decide how to interoperate, enforcing and |
|  |
|  | maintaining standards |
|  | • Recognized objectives, a designated manager, and resources |
| **Acknowledged** | for the SoS |
| • Constituent systems retain their independent ownership, |
|  |
|  | management, and resources |
|  | • Integrated SoS built and managed to fulfill specific purposes |
| **Directed** | • Centrally managed and evolved |
| • Component systems maintain ability to operate independently |
|  | • Normal op mode is subordinated to central purpose |

**Figure G.1 – System of System Types**

**G.3 Systems engineering processes applied to systems of systems**

**G.3.1 General**

The above characteristics of SoS have implications on the application of each of the four types of system life cycle processes.

**G.3.2 Agreement processes**

Agreement Processes are crucial for SoS because they establish the modes of developmental and operational control among the organizations responsible for the SoS and the often independent constituent systems. Constituent systems, which are acquired and managed by different organizations, often hold original objectives that may not align with those of the SoS. Except in the directed SoS case, the SoS organization cannot task a constituent system organization without their cooperation. In an acknowledged or collaborative SoS, these tasks are balanced against the tasks of the constituent system as a SOI in its own right. For virtual SoS, agreement processes may be informal, or considered only for analysis purposes

**G.3.3 Organizational project-enabling processes**

In a typical system-of-interest, Organizational Project-Enabling Processes establish the environment in which projects are conducted. The organization establishes the processes and life cycle models to be used by projects; establishes, redirects, or cancels projects; provides resources required, including human and financial; and sets and monitors the quality measures for systems and other deliverables that are developed by projects for internal and external customers. (Subclause 6.2).

In an SoS, the owners of the constituent systems usually retain responsibility for engineering their systems and they each have their own Organizational Project-Enabling Processes. Depending on the SoS type, the SoS also applies these Organizational Project-Enabling Processes to the particular considerations of the SoS

1. planning, analyzing, organizing, and integrating the capabilities of a mix of existing and new systems into a SoS capability.

Consequently, in SoS these Organizational Project-Enabling Processes are implemented at two levels. The organizations responsible for the constituent systems implement these processes for their SOI independent of the SoS. The SoS organization (or in collaborative systems of systems by agreement of the SoS) implement these processes for the SoS for those considerations that apply to the overall SoS. For example, Human Resource Management is addressed by each constituent system organization for the engineering of their system. The SoS organization would only address this for the systems engineering activities that apply across the constituent systems to the SoS.

A particular challenge in SoS engineering is the lack of alignment among the constituent system Organizational Project-Enabling Processes and those of the SoS. Constituent systems processes are designed to meet their own outcomes and may not align with those of the SoS. For example, Portfolio

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Management will be a constituent system responsibility in cases where the constituent system organization has full control over the constituent system and other systems and projects in its portfolio, and the SoS organization will need an approach to Portfolio Management that recognizes this.

**G.3.4 Technical management processes**

In a typical system-of-interest, Technical Management Processes are concerned with managing the resources and assets allocated by organization management and with applying them to fulfill the agreements into which the organization or organizations enter. They relate to the management of projects, in particular to planning in terms of cost, timescales and achievements; to the checking of actions for compliance with plans and performance criteria; and to the identification and selection of corrective actions that recover shortfalls in progress and achievement. They are used to establish and perform technical plans for the project, manage information across the technical team, assess technical progress against the plans for the system products or services, control technical tasks through to completion, and to aid in the decision-making process (subclause 6.3).

The Technical Management Processes are also implemented at the level of the SoS and that of the constituent systems. Technical Management Processes are applied to the particular considerations of SoS engineering - planning, analyzing, organizing, and integrating the capabilities of a mix of existing and new systems into a system of systems capability. In parallel, the constituent systems organizations retain responsibility for engineering their systems and for their own Technical Management Processes.

The SoS organization addresses the Technical Management process as they apply across the SoS, while the processes are also implemented independently in the constituent system organizations. For configuration management for instance, constituent systems manage their own configurations while the SoS addresses configuration management as it applies to the mix of systems in the SoS. Risk is managed by the constituent systems based on assessment of risk as it applies to their outcomes while the SoS risk management looks at risk to the SoS.

Planning and Assessment and Control are key to all management practices (subclause 6.3; page 31); a key challenge in systems of systems engineering is the lack of control by the SoS organization over the processes for the constituent systems (particularly for acknowledged and collaborative SoS). Driven by their own organizational requirements, each of the constituent systems may be on a development or upgrade schedule that differs from the schedules of other constituent systems. The SoS organization must plan an integrated life cycle that recognizes the independent changes in the constituent systems, in addition to the SoS-initiated changes in a life cycle that treats the SoS as the SOI. This often involves the definition of stable intermediate forms that punctuate the SoS evolution with incremental capabilities added among the constituent systems.

**G.3.5 Technical processes**

Technical Processes are concerned with technical actions throughout the life cycle. They transform the needs of stakeholders first into a product and then, by applying that product, provide a sustainable service, when and where needed in order to achieve customer satisfaction. The Technical Processes are applied in order to create and use a system, whether it is in the form of a model or is a finished product, and they apply at any level in a hierarchy of system structure (Subclause 6.4).

As with the other processes when applied to SoS, Technical Processes are implemented for both the SoS and constituent systems; in some cases, the SoS implementation is by means of conduct of the constituent system processes rather than for the SoS as a whole.

Business or Mission Analysis for an SoS looks across the full SoS business and mission environment. To the degree the constituent system was developed to operate in that space, the Business or Mission Analysis for the systems of system and constituent systems will be largely shared. The objective is to determine the best means to provide the desired capability.

Stakeholder Needs and Requirements Definition will focus on the top level SoS, but also consider how the disparate needs of the stakeholders for the individual systems may lead to constraints on the system of systems.

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System Requirements Definition for the SoS tends to be defined at the level needed to satisfy stakeholder needs and mission objectives, to be translated into requirements for the constituent systems with the SoS serving as "stakeholder" for new requirements for the constituent systems.

The Architecture for the SoS is a framework for organizing and integrating the capabilities of a mix of existing and new systems into a SoS capability, leaving the architectures of the constituent systems to their organizations. Because the constituent systems in an SoS usually predate the SoS, SoS Architecture Definition often begins with the de facto architecture of the SoS. Architecture alternatives are then examined in order to frame stakeholder concerns and meet top level system of system requirements, and to recognize the effect of new requirements for the constituent systems and accommodate the constituent system architecture constraints.

The Design Definition process provides sufficient detailed data and information to enable the SoS implementation. This involves collaboration with the constituent systems who will conduct their own design trades to identify the approach to address SoS requirements as they apply to their system. These are the responsibility of the constituent system organization and Implementation is a done by the constituent system with the SoS organization in a monitoring role.

Integration, Verification, Transition, Validation are all done by the constituent systems for the changes they implement to support requirements generated by the SoS. These processes also apply to the SoS when the upgraded constituent systems are integrated into the SoS and performance is verified and validated. The independent and asynchronous nature of constituent systems in an SoS pose challenges to effective implementation of these processes as implemented in a traditional SOI. It may be that the SoS-level evaluations can only be performed in the operational environment, in which case precautionary measures should be considered to avoid adverse SoS-behavior.

Finally, the Operations, Maintenance and Disposal Processes tend to be implemented by the constituent systems, given their management and operational independence. There may be SoS-level interactions to facilitate those processes.

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**ISO/IEC/IEEE 15288:2015(E)**

**Bibliography**

1. ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*
2. ISO 9001:2008, *Quality management systems — Requirements*
3. ISO 9004:2009, *Managing for the sustained success of an organization — A quality management* *approach*
4. ISO 9241-210:2010, *Ergonomics of human-system interaction — Part 210: Human-centered design for* *interactive systems*
5. ISO 10004:2012, *Quality management — Customer satisfaction* *―* *Guidelines for monitoring and* *measuring*
6. ISO 10007:2003, *Quality management systems — Guidelines for configuration management*
7. ISO/IEC 10746-3:2009, *Information technology — Open distributed processing — Reference model:* *Architecture*
8. ISO 14001:2004, *Environmental management systems — Requirements with guidance for use*
9. ISO/IEC 15026-3:2011, *Systems and software engineering — Systems and software assurance — Part 3:* *System integrity levels*
10. ISO/IEC 15026-4, *Systems and software engineering — Systems and software assurance — Part 4:* *Assurance in the life cycle*
11. ISO/IEC/IEEE 15289:2011, *Systems and software engineering — Content of life cycle information* *products (documentation)*
12. ISO/IEC 15504 (multiple parts), *Information Technology — Process assessment*
13. ISO 15704:2000, *Industrial automation systems — Requirements for enterprise-reference architectures* *and methodologies*
14. ISO/IEC 15939:2007, *Systems and software engineering — Measurement process (IEEE Std 15939-2008,* *Adoption of ISO/IEC 15939:2007, Systems and software engineering — Measurement process)*
15. ISO/IEC 16085:2006, *Systems and software engineering — Life cycle processes — Risk management*
16. ISO/IEC/IEEE 16326:2009, *Systems and software engineering — Life cycle processes — Project* *management*
17. ISO/TS 18152:2010, *Ergonomics of human-system interaction — Specification for the process* *assessment of human-system issues*
18. ISO/TR 18529:2000, *Ergonomics — Ergonomics of human-system interaction — Human-centred lifecycle* *process descriptions*
19. ISO/IEC 20000-1:2011, *Information technology — Service management — Part 1: Service management* *system requirements* (IEEE Std 20000-1:2013)
20. ISO/IEC TR 24748-1:2010[1](#page114), *Systems and software engineering — Life cycle management — Part 1:* *Guide for life cycle management (IEEE Std 24748-1-2011, IEEE Guide — Adoption of ISO/IEC TR 24748-*
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**ISO/IEC/IEEE 15288:2015(E)**

*1:2010 Systems and Software Engineering — Life Cycle Management — Part 1: Guide for Life Cycle Management)*

1. ISO/IEC TR 24748-2:2011, *Systems and software engineering — Life cycle management — Part 2: Guide* *to the application of ISO/IEC 15288 (System life cycle processes) (IEEE Std 24748-2-2012, IEEE Guide— Adoption of ISO/IEC TR 24748-2:2011 Systems and Software Engineering—Life Cycle Management— Part 2: Guide to the Application of ISO/IEC 15288 (System Life Cycle Processes))*
2. ISO/IEC/IEEE 24748-4:—[2](#page115) , *Systems and software engineering — Life cycle management — Part 4:* *Systems engineering planning*
3. ISO/IEC/IEEE 24765:2010, *Systems and software engineering — Vocabulary*
4. ISO/IEC TR 24774:2010[3](#page115), *Systems and software engineering — Life cycle management — Guidelines for* *process description*
5. ISO/IEC 25010:2011, *Systems and software engineering — Systems and software Quality Requirements* *and Evaluation (SQuaRE) — System and software quality models*
6. ISO/IEC 25030:2007, *Software engineering — Software product Quality Requirements and Evaluation* *(SQuaRE) — Quality requirements*
7. ISO/IEC TR 25060:2010, *Systems and software engineering — Systems and software product Quality* *Requirements and Evaluation (SQuaRE) — Common Industry Format (CIF) for usability: General framework for usability-related information*
8. ISO/IEC 25063:2014, *Systems and software engineering — Systems and software product Quality* *Requirements and Evaluation (SQuaRE) — Common Industry Format (CIF) for usability: Context of use description*

|  |
| --- |
| --`,,`,,,`,``,,,`,`,``,``,,,,,,`-`-`,,`,,`,`,,`--- |

1. ISO/IEC/IEEE 26531:—[4](#page115), *Systems and software engineering — Content management for product life* *cycle, user and service management documentation*
2. ISO/IEC 27036 (multiple parts), *Information technology — Security techniques — Information security for* *supplier relationships*
3. ISO/IEC/IEEE 29148:2011, *Systems and software engineering — Life cycle processes — Requirements* *engineering*
4. ISO 31000:2009, *Risk management — Principles and guidelines*
5. ISO/IEC 33002:— [5](#page115) , *Information technology* *―* *Process assessment* *―* *Requirements for performing* *process assessment*
6. ISO/IEC/IEEE 42010:2011, *Systems and software engineering — Architecture description*
7. IEC 61508 (multiple parts), *Functional safety of electrical/electronic/ programmable electronic safety-related systems*
8. ISO Guide 73:2009, *Risk management — Vocabulary*
9. ANSI/AIAA G-043A-2012e, *ANSI/AIAA Guide to the Preparation of Operational Concept Documents*

2 To be published. (Revision of ISO/IEC 26702:2007)

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4 To be published.

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**ISO/IEC/IEEE 15288:2015(E)**

1. ANSI EIA-649-B-2011, *Configuration Management Standard*
2. IEEE Std 828-2012, *IEEE Standard for Configuration Management in Systems and Software Engineering*
3. INCOSE-TP-2003-002-03.2.2, Systems Engineering Handbook, *A Guide for System Life Cycle Processes* *and Activities*, October 2011
4. INCOSE-TP-2003-020-01, *Technical Measurement*, Version 1.0, 27 December 2005
5. NATO AEP-67, *Engineering for System Assurance in NATO Programs*
6. SAE ARP4754A:2010, *Guidelines for Development of Civil Aircraft and Systems*
7. SAE JA1011:2009, *Evaluation Criteria for Reliability-Centered Maintenance (RCM) Processes*

|  |
| --- |
| --`,,`,,,`,``,,,`,`,``,``,,,,,,`-`-`,,`,,`,`,,`--- |

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**ISO/IEC/IEEE 15288:2015(E)**

**Abstract:** A common framework for describing the life cycle of systems created byhumans is established by this standard. It defines a set of processes and associated terminology. These processes can be applied at any level in the hierarchy of a system's structure. Selected sets of these processes can be applied throughout the life cycle for managing and performing the stages of a system's life cycle. This is accomplished through the involvement of all interested parties, with the ultimate goal of achieving customer satisfaction.

This International Standard also provides processes that support the definition, control and improvement of the life cycle processes used within an organization or a project. Organizations and projects can use these life cycle processes when acquiring and supplying systems. This International Standard concerns those systems that are man-made and may be configured with one or more of the following: hardware, software, data, humans, processes (e.g., processes for providing service to users), procedures (e.g., operator instructions), facilities, materials and naturally occurring entities. When a system element is software, the software life cycle processes documented in ISO/IEC 12207:2008 may be used to implement that system element. The two standards are harmonized for concurrent use on a single project or in a single organization. When the system element is hardware, refer to other International Standards outside the scope of SC7.

**Keywords:** 15288, life cycle, life cycle process, software

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