

Systems and Software Engineering

Generic Profile Group: Basic Profile Guide for Safety Critical Very Small Entities

DRAFT

Generic Profile Group: Safety Critical Basic Profile Guide Based on ISO/IEC TR 29110-5-6-2:2014(E)

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1. Introduction

Very Small Entities (VSEs) around the world are contributing to valuable products and services. For the purpose of ISO/IEC 29110, a Very Small Entity (VSE) is an enterprise, an organization, a department or a project having up to 25 people. Since many VSEs develop and/or maintain system elements and software components used in systems, or sold to be used by others, recognition of VSEs as suppliers of high quality products is required.

From studies and surveys conducted, it is clear that the majority of International Standards do not address the needs of VSEs. Implementation of and conformance with these standards is difficult, if not impossible. Subsequently VSEs have no, or very limited, ways to be recognized as entities that produce quality systems/system elements including software in their domain. Therefore, VSEs are often cut off from some economic activities.

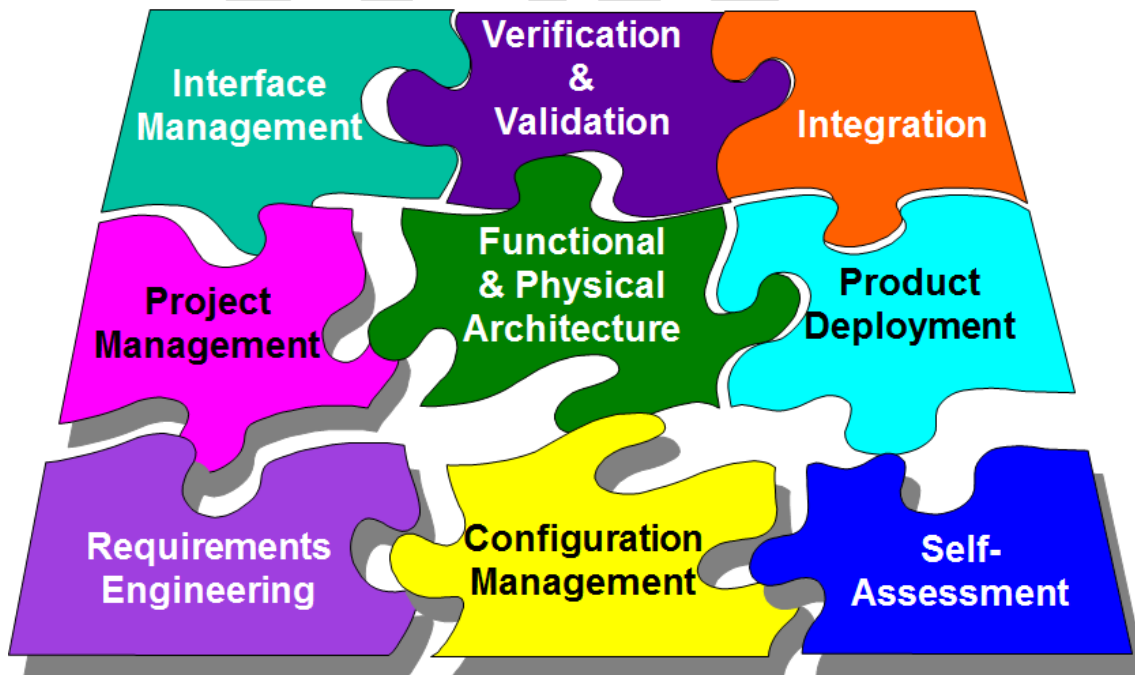
ISO/IEC 29110 is intended to be used with any lifecycles such as: waterfall, iterative, incremental, evolutionary or agile. The ISO/IEC 29110 series, targeted by audience, has been developed to improve system or software and/or service quality, and process performance.

1.1 Systems Engineering Deployment Packages

In order to facilitate the implementation, by VSEs, of a Profile, a set of Deployment Packages are available. A deployment package is a set of artefacts developed to facilitate the implementation of a set of practices, of the selected framework, in a VSE. But, a deployment package is not a complete process reference model. Deployment packages are not intended to preclude or discourage the use of additional guidelines that VSEs find useful.

The elements of a typical deployment package are: technical description, relationships with ISO/IEC 29110, key definitions, detailed description of processes, activities, tasks, steps, roles, products, template, checklist, example, references and mapping to standards and models, and a list of tools.

Hence by deploying and implementing a package, a VSE can see its concrete step to achieve or demonstrate coverage to Part 5. Deployment Packages are designed such that a VSE can implement its content, without having to implement the complete framework at the same time.



The Nine (9) Deployment Packages

- | | | |
|------------------------------------|--------------------------------|-----------------------------|
| 1. System Requirements Engineering | 3. Interface Management | 6. Configuration Management |
| 2. System Architecture | 4. System Integration | 7. Project Management |
| | 5. Verification and Validation | |

Table of Content of a System Engineering Deployment Package:

1. Technical Description

- Purpose of this document
- Why this Topic is important?

2. Definitions

3. Relationships with ISO/IEC 29110

4. Overview of Processes, Activities, Tasks, Roles and Products

5. Description of Processes, Activities, Tasks, Steps, Roles and Products

- Role Description
- System Description
- Artefact Description

6. Template(s)

7. Example(s)

8. Checklist(s)

9. Tool(s)

10. References to other Standards and Models (e.g. ISO 9001, ISO/IEC 15288, CMMI-DEV®)

11. References

12. Evaluation form

For the Basic Profile, a set of Systems Engineering Deployment Packages are available, at no cost, on the Internet:

1. System Requirements Engineering
2. System Architecture
3. Interface Management
4. System Integration
5. Verification and Validation
6. Configuration Management
7. Project Management
8. System Deployment
9. Self-Assessment

2. Scope

2.1 Fields of application

This kit is applicable to Very Small Entities (VSEs). VSEs are enterprises, organizations, departments or projects having up to 25 people. The lifecycle processes described in the set of International Standards (IS) and Technical Reports (TR) are not intended to preclude or discourage their use by organizations bigger than VSEs.

This kit provides the management and engineering guide to the Basic Profile described in ISO/IEC 29110-4-6 through Project Management and System Definition and realization processes. This kit should be used in conjunction with ISO/IEC 29110.

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This kit is for critical systems development projects. The system development should fulfil the project requirements and the system description.

Using the kit a VSE can obtain benefits in the following aspects:

- An agreed set of project requirements (technical part of contract) and expected products are agreed by the Acquirer.
- A disciplined management process, that provides project visibility and corrective actions of project problems and deviations, is performed.
- A systematic System Definition and Realization process, that satisfies Acquirer needs and ensures quality products, is followed.
- VSEs developing software that is part of a larger system, and for stand-alone software products and services, are encouraged to use the management and engineering guide of the Basic Profile

2.2 Target Audience

This kit is targeted at VSEs who develop critical systems and do not have experience with SE process planning and implementation using ISO/IEC 15288.

It is intended to be used with any processes, techniques and methods that enhance the VSE's Stakeholder satisfaction and productivity. This guide is to be used in conjunction with critical safety standards, specifications, guidance, and any other information that guides the industry for which this product is being developed.

2.3 Normative References

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/IEC TR 29110-1, Software engineering — Lifecycle profiles for Very Small Entities (VSEs) — Part 1: Overview

Required Documents

Document	Description
SOURCE: INCOSE:2010	
ISO/IEC 15288:2008, modified	
(AS/EN/JIS Q) 9100:2009	
OECD 2005	
ISO/IEC 12207:2008	
SOURCE: ISO/IEC 12207:2008	

Documents <i>[Specific to your Industry]</i>	Description

Terms and definitions

Term	Definition
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Term	Definition
acquirer	stakeholder that acquires or procures a product or service from a supplier
critical system	those items (e.g. functions, parts, software, characteristics, processes) having significant effect on the product realization and use of the product – including safety, performance, form, fit, function, producibility, service life, etc. – that require specific actions to ensure they are adequately managed
disposed system	system that has been transformed (i.e. state change) by applying the disposal process
operator	entity that performs the operations of a system
Systems Engineering Plan (SEP)	top-level plan for managing the SE effort which, as such, defines how the project will be organized, structured, and conducted and how the total engineering process will be controlled to provide a product that satisfies stakeholder requirements
Small and Medium Enterprise	enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding 50 million euro, and/or an annual balance sheet total not exceeding 43 million euro)
system	combination of interacting elements organized to achieve one or more stated purposes
trade-off	decision-making actions that select from various requirements and alternative solutions on the basis of net benefit to the stakeholders
system structure	decomposition of a system of interest into a set of interacting systems and system elements
statement of work	document used by the acquirer that includes the needs and expectations, the scope, objectives and deliverables
work breakdown structure	[Output/Input] deliverable-oriented hierarchical decomposition of the work to be executed by the project team to accomplish the project objectives and create the required deliverables

3 Symbols and abbreviated terms

3.1 Naming, diagramming and definition conventions

Term	Description
Name	Process identifier, followed by its abbreviation in brackets "()".
Purpose	General goals and results expected of the effective implementation of the process. The implementation of the process should provide tangible benefits to the stakeholders. The purpose is identified by the abbreviation of the process name.
Objectives	Specific goals to ensure the accomplishment of the process purpose. The objectives are identified by the abbreviation of the process name, followed by the letter "O" and a consecutive number, for example PM.O1, SR.O2, etc.
Input Products	Products required to perform the process and its corresponding source, which can be another process or an external entity to the project, such as the Acquirer. Identified by the abbreviation of the process name and showed as two column table of product names and sources.
Output Products	Products generated by the process and its corresponding destination, which can be another process or an external entity to the project, such as Acquirer or Organizational Management. Identified by the abbreviation of the process name and showed as two column table of product names and destinations.
Internal Products	Products generated and consumed by the process. Identified by the abbreviation of the process name and showed as one column table of the product names. All products' names are printed in cursive and initiate with capital letters. Some products have one or more statuses attached to the product name surrounded by square brackets "[]" and separated by ";". The product status may change during the process execution. See Product Descriptions table in ISO/IEC TR 29110-5-6-2 for the alphabetical list of the products, its descriptions, possible statuses and the source of the product. The source can be another process or an external entity to the project, such as the Acquirer.
Rectangle boxes	The rectangle boxes following the description of processes objectives make the correspondence with ISO/IEC 15288:2008 standard.
Roles involved	Names and abbreviation of the functions to be performed by project team members. Several roles may be played by a single person and one role may be assumed by several persons. Roles are assigned to project participants based on the characteristics of the project. The role list is identified by the abbreviation of the process name and showed as two-column table. See the Roles section in this document for the alphabetical list of the roles, its abbreviations and required competencies description.
Diagram	Graphical representation of the processes. The large round-edged rectangles indicate process or activities and the smaller square-edged rectangles indicate the products. The directional or bidirectional thick arrows indicate the major flow of information between processes or activities. The thin directional or bidirectional arrows indicate the input or output products. The notation used in the diagrams does not imply the use of any specific process lifecycle.
Activity	A set of cohesive tasks. Task is a requirement, recommendation, or permissible action, intended to contribute to the achievement of one or more objectives of a process. A process activity is the first level of process workflow decomposition and the second one is a task. Activities are identified by process name abbreviation followed by consecutive number and the activity name.
Activity Description	Each activity description is identified by the activity name and the list of related objectives surrounded by brackets "()". For example PM.1 Project Planning (PM.O1, PM.O5, PM.O6, PM.O7) means that the activity PM.1 Project Planning contributes to the achievement of the listed objectives: PM.O1, PM.O5, PM.O6 and PM.O7. The activity description begins with the task summary and is followed by the task descriptions table. The task description doesn't impose any technique or method to perform it. The selection of the techniques or methods is left to the VSE or project team.
Incorporation to Project Repository	List of products to be saved in <i>Project Repository</i> ; the <i>Configuration Management Strategy</i> has to be applied to some of them See Section 7.7.2 PM incorporation to Project Repository and 8.7.2 SR incorporation to the Project Repository in ISO/IEC TR 29110-5-6-2 . It is useful as a checklist for project manager and technical leader.

3.2 3.2 Abbreviated Terms

Acronym	Term
ACQ	Acquirer
HW	Hardware
IVV	Integration, Verification, Validation
PO	Purchase Order
PM	Project Management
PJM	Project Manager
SBS	System Breakdown Structure
SDD	System Design Document
SEMP	System Engineering Management Plan
SEP	Systems Engineering Plan
SMART	Specific, Measurable, Achievable, Relevant and Traceable
SME	Small and Medium Enterprise
SBS	System Breakdown Structure
SOW	Statement of Work
SR	System Definition and Realization
STK	Stakeholder
SW	Software
TPM	Technical Performance Management
VSE	Very Small Entity
WBS	Work Breakdown Structure

4 Overview

The Basic Profile Management and Engineering Guide applies to a Very Small Entity (VSE), i.e. enterprise, organization, department or project having up to 25 people, dedicated to system development of critical systems. The project may fulfil an external or internal contract. The internal contract between the project team and its Acquirer need not be explicit. The Guide provides Project Management (PM) and System Definition and Realization (SR) processes which integrate practices based on the selection of ISO/IEC 15288, *Systems and software engineering —System life cycle processes* and ISO/IEC/IEEE 15289, *Systems and software engineering – Content of lifecycle information products (documentation)* standards elements. Annex A provides information about

This part of ISO/IEC 29110 is intended to be used by the VSE to establish processes to implement any development approach or methodology including, e.g. agile, evolutionary, incremental, test driven development, etc. based on the VSE organization or project needs.

Using this Kit, VSE can obtain benefits in the following aspects:

- A set of project requirements (technical part of the contract) and expected products are agreed with the Acquirer.
- A disciplined management process, that provides project visibility and corrective actions of project problems and deviations, is performed;
- A systematic System Definition and Realization process, that satisfies Acquirer needs and ensures quality products, is followed.

To use the Kit the VSE needs to fulfil the following entry conditions:

- Project *Needs and Expectations* are documented;
- Feasibility of the project was performed before its start;
- Project team, including project manager and system engineer, is assigned and trained; and
- Goods, services and infrastructure to start the project are available.

Tasks Description Table Form:

Role	Task	Input Products	Output Products
The abbreviation of roles	Description of the task to be	Products needed to	Products created or

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involved in the task execution.	performed. Each task is identified by activity ID and consecutive number, for example PM1.1, PM1.2, and so on.	execute the task.	modified by the execution of the task.
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5 Project Management (PM) Process

5.1 PM Purpose

The purpose of the Project Management process is to establish and carry out in a systematic way the *Tasks* of the system development project, which allows complying with the project's *Objectives* in the expected quality, time and costs.

This kit is intended to be used by the VSE to establish processes to implement any development approach or methodology including, e.g. agile, evolutionary, incremental, test driven development, etc. based on the VSE organization or project needs.

In a regulated industry, this document provides references to guidance that handles regulations and standards that apply to your industry.

The references are called out throughout this kit.

5.2 PM Objectives

These objectives may need document artifacts, archives, and evidence required by your regulated body.

PM.O1. The *Project Plan*, the *Statement of Work (SOW)* and commitments are reviewed and accepted by both the Acquirer and the Project Manager. The *Tasks* and *Resources* necessary to complete the work are sized and estimated.

PM.O2. Progress of the project is monitored against the *Project Plan* and recorded in the *Progress Status Record*. Corrections to remediate problems and deviations from the plan are taken when project targets are not achieved. Closure of the project is performed to get the Acquirer acceptance documented in the *Product Acceptance Record*.

PM.O3. *Change Requests* are addressed through their reception and analysis. Changes to system requirements are evaluated by the project team for cost, schedule, risks and technical impact.

PM.O4. Review meetings with the Work Team and the Acquirer, suppliers are held. Agreements are registered and tracked.

PM.O5. A *Risk Management Approach* is developed. Risks are identified, analyzed, prioritized, and monitored as they develop and during the conduct of the project. Resources to manage the risks are determined.

PM.O6. A *Product Management Strategy* is developed. Items of *Product* are identified, defined and baselined. Modifications and releases of the items are controlled and made available to the Acquirer and Work Team. The storage, handling and delivery of the items are controlled.

PM.O7. Quality Assurance is performed to provide assurance that work products and processes comply with the *Project Plan* and *System Requirements Specifications*.

NOTE: The implementation of the Quality Assurance is through the performance of the verifications, validations and review *Tasks* performed in Project Management and System Definition and Realization processes.

PM.O8. A *Disposal Management Approach* is developed to end the existence of a system entity.

Table 1 — PM Input Products

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Name	Source
Statement of Work	Acquirer
All deliverables from SR	Work Team
Change Request	Acquirer, Stakeholders Work Team Suppliers

Table 2 — PM Output Products

Name	Source
Project Plan	System Definition and Realization
Product Acceptance Record	Organizational Management
Project Repository	System Definition and Realization
Meeting Record	Acquirer, Stakeholders
Product	Acquirer, Stakeholders System Definition and Realization Suppliers
Purchase order	Suppliers

Table 3 — PM Internal Products

Name
Change Request
Correction Register
Justification Document
Meeting Record
Progress Status Record
Project Repository
Product Acceptance Record
Verification Report

Table 4 — PM roles involved

Role	Abbreviation
Acquirer	ACQ
Stakeholders	STK
Project Manager	PJM
Work Team	WT
Designer	DES
Systems Engineer	SYS

5.3 PM diagram

The following diagram shows the flow of information between the Project Management Process activities

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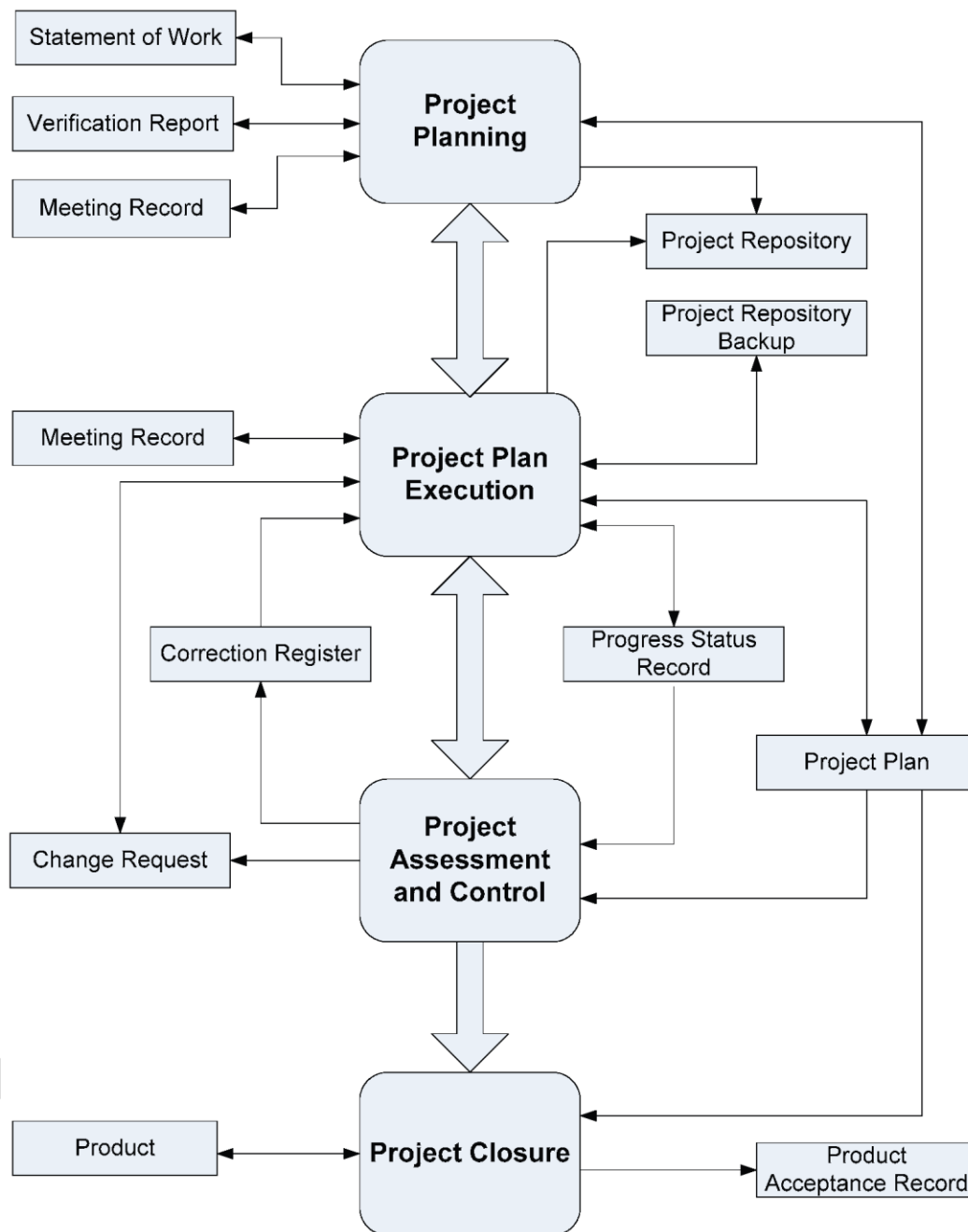


Figure 3 — Project Management process diagram

5.4 Project Management Activities

Project Management Activities should be tailored by the Working Group to comply with policies of the domain.

PM.1 Project Planning, (PM.O1, PM.O5, PM.O6, PM.O7)

The Project Planning activity documents the planning details needed to manage the project. The activity provides:

- Reviewed Statement of Work (SOW) and the Tasks needed to provide the contract Deliverables.
- System Breakdown Structure (SBS), to provide the list of system and system elements of the project.
- Project life cycle, including task dependencies and duration.

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- Project quality assurance strategy through verification and validation of work products/Deliverables, Acquirer, Stakeholders and Work Team reviews.
- Work Team, Acquirer and other Stakeholders roles and responsibilities.
- Project Resources and training needs.
- Estimates of effort cost and schedule.
- Risk Management Approach.
- Disposal Management Approach.
- Change Control Process and Configuration Management strategy.
- Project Repository to store, handle and deliver controlled product and document versions and baselines.

PM.2 Project Plan Execution (PM.O2, PM.O3, PM.O4, PM.O5, PM.O7)

The Project Plan Execution activity implements the documented plan on the project. The activity provides:

- *Progress Status Record* of the project updated.
- Analyzed and evaluated change requests to the plan impacting cost, schedule and technical requirements.
- Approved changes to the plan.
- Reviews and agreements with the Work Team (WT), Acquirer (ACQ) and Stakeholders (STK).
- Back up of the *Project Repository*, and its recovery if necessary.

PM.3 Project Assessment and Control (PM.O2)

The Project Assessment and Control activity evaluates the performance of the plan against documented commitments. The activity provides:

- The Project Assessment and Control activity evaluates the performance of the plan against documented commitments. The activity provides:
- Evaluation of actual plan performance and progress against targets.
- Identified and evaluated significant cost, schedule and technical performance deviations and problems.
- Review of project risks and identification of new risks.
- Documented change requests, appropriate corrective action defined, and changes tracked to closure.

PM.4 Project Closure (PM.O2, PM.O8)

The Project Closure activity provides the project's documentation and products in accordance with contract requirements. The activity provides:

- Delivery of the product as specified in the *Delivery Instructions*.
- Support of Acquirer and Stakeholders product acceptance in accordance to *Delivery Instructions*.
- Completion of the project and sign of the *Acceptance Record*.
- Execution of the *Disposal Management Approach*.

5.5 PM Incorporation to Project Repository

The list of products to be saved in *Project Repository*. After the incorporation, *Configuration Management Strategy* has to be applied to *Project Plan*.

Table 5 — PM Repository Products

Product
<i>Project Plan</i>
<i>Change Request</i>
<i>Product Acceptance Record</i>
<i>Meeting Record</i>
<i>Correction Register</i>
<i>Progress Status Record</i>
<i>Purchase Order</i>
<i>Verification Report</i>
<i>Validation Report</i>
<i>Delivery Instructions</i>

Table 6 — Project Management Tools

Activity	Resource Documents
Project Planning Project Plan Execution Project Assessment and Control Project Closure	Tool allowing document, manage and control the <i>Project Plan</i> . Tool allowing Project scheduling, tasks definition, resources and cost management. Tool allowing the measurement of the project execution Tool to manage project configuration and changes.

6 System Definition and Realization (SR) process

6.1 SR Purpose

The purpose of the System Definition and Realization process is the systematic performance of the specification of system/system element, analysis, design, construction, integration, and verification/validation activities for new or modified systems according to the specified requirements.

Certification process activities required by the domain should be tailored to the project profile.

This section does not prescribe nor establish processes to implement any development approach or methodology.

SR.O1 Example refers to the **Mapping between the objectives of ISO/IEC TR 29110-5-6-2 and ISO/IEC 15288:2008** found in **Annex B (informative)** in the **ISO/IEC TR 29110-5-6-2** document. These tables can be used to develop your basic deployment packages.

SR.O1 Example

6.3.1 Project planning process
d) Plans for the execution of the project are activated and maintained.

[ISO/IEC 15288:2008, 6.3.1]

6.2 SR Objectives

Consider these objectives and address additional steps required by you domain.

SR.O1. Tasks of the activities are performed through the accomplishment of the current *Project Plan*.

SR.O2. System requirements are defined, analyzed for correctness and testability, approved by the Acquirer, baselined and communicated.

SR.O3. The System architectural design is developed and baselined. It describes the *System elements* and internal and external interfaces of them. Consistency and traceability to system requirements are established.

NOTE: System architecture and detailed design can be performed separately according to the project schedule.

SR.O4. System elements defined by the design are produced or acquired. Acceptance tests are defined and performed to verify the consistency with requirements and the design. Traceability to the requirements and design are established.

SR.O5. System elements are integrated. Defects encountered during integration are corrected and consistency and traceability to *System Architecture* are established.

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SR.O6. A *System Configuration*, as agreed in the Project Plan, and that includes the engineering artefacts is integrated, baselined and stored at the *Project Repository*. Needs for changes to the *Product* are detected and related change requests are initiated.

SR.O7. Verification and Validation *Tasks* of all required work products are performed using a defined criteria to achieve consistency among output and input products in each activity. Defects are identified, and corrected; records are stored in the *Verification/Validation Reports*.

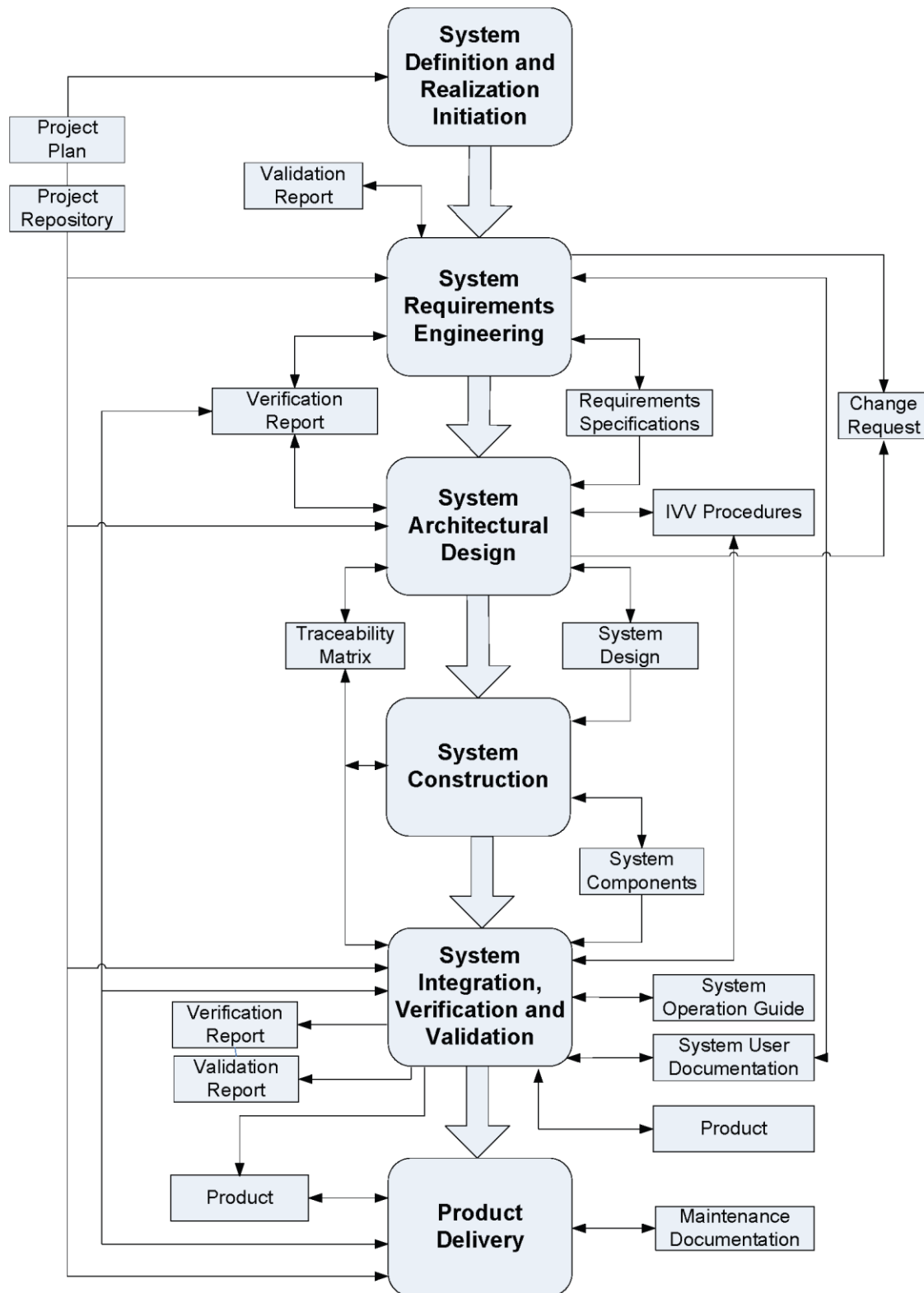
NOTE: It's not the intention that all verification activities and work products are made available to the acquirer and other stakeholders. Verifications should be performed by individuals that have organizational freedom, authority, to permit objective evaluation, and to initiate, effect, resolve and verify problem resolution.

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6.3 SR diagram

Overview SR diagram

The following diagram shows the flow of information between the System Definition and Realization Process activities including the most relevant work products and their relationship.



6.4 SR Activities

These activities are required to be covered by the deployment package. System Definition and Realization Activities should be tailored by the Working Group to comply with policies of the domain.

SR.1 System Definition and Realization Initiation (SR.O1)

The System Definition and Realization Initiation activity ensures that the *Project Plan* established in Project Planning activity is committed to by the Work Team. The activity provides:

- Review of the *Project Plan* by the Work Team to determine task assignment.
- Commitment to *Project Plan* by the Work Team and Project Manager.
- An established implementation environment.

The System Definition and Realization Initiation activity must ensure that the qualifications and certification activities are addressed as required by the domain.

SR.2 System Requirements Engineering (SR.O2, SR.O6, SR.O7)

The System Requirements Engineering activity elicits and analyses the Acquirer and other Stakeholders' requirements, including legal and/or regulatory requirements. It establishes the agreed system requirements. In parallel of the architectural design activities, it establishes System Element requirements. The activity provides:

- *Domain specific lifecycle Stakeholders need to be identified and documented*
- Work Team review of the *Project Plan* to determine task assignment
- Elicitation, analysis and specification of Acquirer and other stakeholders' requirements.
- Specification and agreement on the System requirements.
- Specification of system elements' requirements
- Verification of implemented system against System and System elements requirements
- Validation of Stakeholder, System and System Elements requirements
- Validation of implemented system against Stakeholder requirements
- Establish and update the traceability between Stakeholders, System, System Elements requirements
- Establish and update the coverage of Requirements by IVV artefacts
- Configuration management of System Requirements Engineering products as agreed in the Configuration Management Plan

SR.3 System Architectural Design (SR.O3, SR.O6, SR.O7)

The System Architectural activity transforms the system requirements to the system operational, behavioral, and physical architecture. The activity provides:

- Domain specific system architectural constraints need to be identified and documented
- Work Team review of the *Project Plan* to determine task assignment.
- Design the system **functional** architecture and associated interfaces.
- Design the system physical architecture and associated interfaces, allocation of the functional to the physical architecture.
- Work Team review of the *System Requirements Specifications*.
- **Functional and physical Design** verified and defects corrected.
- Verified IVV Plan (*Integration, Verification, validation, Qualification*) and Verification Procedures.
- Traceability between the functional architecture definition and the System Requirements and between the physical architecture definition, the System Elements and the functional architecture definition.
- Design products placed under configuration management
- Considerations for allocations should be taken for mission resources, personnel, equipment (hardware/software), and procedural data

SR.4 System Construction (SR.O4, SR.O6, SR.O7)

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The System Construction involves Physical Construction and/or Software Construction. The Software Construction develops the software elements of the system from the *System Design*. The Hardware Construction develops the Hardware system elements from the *System Design*, that include, system resources, procedural data, (or not) software elements. The activity provides:

- Work Team review of the *Project Plan* to determine task assignment.
- Work Team review of the *Software Design*
- Work Team review of the *Physical Design*
- *Hardware System Elements* to be developed and tested.
- *Software System Elements* to be developed and tested.
- Traceability between *Hardware Construction*, *Software Construction* and *Physical Architecture*

SR.5 System Integration, Verification, and Validation (SR.O5, SR.O6, SR.O7)

The System Integration verification, and validation activity ensures that the integrated System Elements satisfy the system requirements, documented intended uses and needs of the stakeholders in its intended environment. The activity provides:

- Work Team review of the *Project Plan* to determine task assignment.
- Understanding of *IVV plan and Procedures* and the integration environment.
- Integrated *System Elements*, corrected defects and documented results.
- Documented and verified operational and system user documentations.
- Verified System baseline.

SR.6 Product Delivery (SR.O6, SR.O7)

The Product Delivery activity provides the integrated System to the Acquirer. The activity provides:

- Work Team review of the *Project Plan* to determine task assignment.
- Delivery of the *Product* and applicable system documentation in accordance with the *Delivery Instructions*.

SR Incorporation to the Project Repository

The list of products to be saved in the *Project Repository* are found in **ISO/IEC TR 29110-5-6-2:2014(E) in the project repository section**. After the incorporation, the *Configuration Management* has to be applied to: *System Requirements Specifications*, *System Design*, *Traceability Matrix*, *IVV Plan and IVV Procedure*, *System Elements (Hardware, Hardware + Software, Software)*, *System*, *System Operation Guide*, *System User Documentation*, *Maintenance and Training Documentation*.

Table 10 — System Definition and Realization Tools

Activity	Resource Documents
System Definition and Realization Initiation System Requirements Engineering System Design System Integration System Verification Product Delivery	<ul style="list-style-type: none">• Requirements Engineering tool allowing elicitation, definition, management and traceability of requirements through the system life cycle (including exchanges with suppliers).• Design tool allowing definition of the functional and physical architecture, definition of interfaces and traceability to the Requirements (including modelling tools).• Tools allowing integration, verification, validation, qualification of the system.• Tool to manage defects within a configuration management process• Tools allowing training the stakeholders in the delivery phase to the use and maintenance of the system. Tools for documentation management.
System Construction	Construction Tools allowing developing the products of the system (hardware, software).

7 Roles

There are extensive and detailed descriptions of the roles found in ISO/IEC TR 29110-5-6-2:2014(E). This information should be used in conjunction with the 9 deployment packages.

This is an alphabetical list of the roles, their abbreviations and suggested competencies description.

Table 10 — Roles

	Role	Abbreviation	Competency
1	Acquirer	ACQ	<ul style="list-style-type: none"> The Acquirer is the Stakeholders representative. This person is responsible for the acquisition of the System. The acquirer may be internal or external to the supplier organization. Acquisition of a product may involve, but does not necessarily require, a legal contract or a financial transaction between the acquirer and supplier. In some context the Acquirer is the end user of the system. Knowledge of the Stakeholders processes and ability to explain the Stakeholders requirements. The Acquirer is the role of the organization that receives the product or service. In some context the Acquirer is the end user of the system. The Acquirer must have the authority to approve the requirements and their changes. The Stakeholders includes user representatives in order to ensure that the operational environment is addressed. Knowledge and experience in the application domain.
2	Designer	DES	<ul style="list-style-type: none"> Knowledge and experience in the architecture design. Knowledge of the revision techniques. Knowledge and experience in the planning and performance of integration tests. Knowledge of the editing techniques. Experience on the system development and maintenance.
3	Developer	DEV	<ul style="list-style-type: none"> Knowledge in fabrication, development (HW, SW) Knowledge and experience in the application domain
4	IVV Engineer	IVV	<ul style="list-style-type: none"> Knowledge of the Requirements, Design Knowledge in inspection, peer review, simulation, and review techniques Knowledge in testing techniques
5	Project Manager	PJM	Leadership capability with experience making decisions, planning, personnel management, delegation and supervision, finances and system development.
6	Stakeholder	STK	<ul style="list-style-type: none"> Stakeholders are actors that have an interest in the system, all along its life cycle, such as, representatives of users, users, maintainers, security, trainers, regulatory bodies, suppliers. STK should have Knowledge of the Stakeholder (e.g. manufacturer, maintainer, tester, logistic) processes and ability to explain the Stakeholder requirements. The Stakeholder (representative) must have the authority to approve the requirements and their changes. Knowledge and experience in the application domain.
7	Supplier	SUP	Supplier of a System Element of the system: hardware, software, or hardware with software.
8	System Engineer	SYS	<ul style="list-style-type: none"> Knowledge and experience eliciting, specifying and analyzing the requirements. Knowledge in designing user interfaces and ergonomic criteria. Knowledge of the revision techniques. Knowledge of the requirements authoring. Knowledge of the business domain Experience on system development, integration, operation and maintenance Experience on the system development and maintenance.
9	Work Team	WT	<ul style="list-style-type: none"> Knowledge and experience according to their roles on the project: <ul style="list-style-type: none"> SYS, DES, DEV, IVV.

		<ul style="list-style-type: none"> • Knowledge on the standards used by the Acquirer and/or by the VSE.
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8 Project and System Design Artifacts

Section 10 of ISO/IEC TR 29110-5-6-2:2014(E) provides an exhaustive list in project and system design artifacts for nominal product development activities. **Table 23** in **Section 10** provides brief descriptions of each artifact. The list of artifacts for an individual product development activity should be tailored to meet the organizational and domain needs. The table is provided here but, refer to the standard for accuracy.

Table 11 — Product Descriptions

	Name	Description	Source
1.	Change Request	Identifies a <i>System</i> , or documentation problem or desired improvement, and requests modifications. It may have the following characteristics: <ul style="list-style-type: none"> • Identifies purpose of change • Identifies request status • Identifies requester contact information • Impacted system(s), system element(s) • Impacted IVV facilities • Impact to operations of existing system(s) defined • Impact to associated documentation defined • Criticality of the request, date needed The applicable statuses are: submitted, evaluated, approved, rejected, postponed	System Definition and Realization Project Management
2.	Correction Register	Identifies activities established to correct a deviation or problem concerning the accomplishment of a plan. It may have the following characteristics: <ul style="list-style-type: none"> • Identifies the initial problem • Defines a solution • Identifies corrective actions taken • Identifies the ownership for completion of defined actions • Identifies the open date and target closure date • Contains a status indicator • Indicates follow up actions • Includes rational of deviation correction action The applicable statuses are: initial, published	Project Management
3.	Data Model	Defines the properties and relations between entities of a project. It may include: <ul style="list-style-type: none"> • Requirements • Functions • System elements • IVV plans • IVV results • Justification elements 	Project Management
4.	Disposed System	A system that has been transformed (i.e. state change) by applying the disposal process	
5.	Implementation Environment	The environment and tools (software and hardware) required to specify, design, develop, integrate, verify, validate, manage the configuration and deploy the system.	System Definition and Realization
6.	Integration Report	Document the integration execution. It may include the record of: <ul style="list-style-type: none"> • Reference to the related IVV procedures • Date 	System Definition and Realization

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		<ul style="list-style-type: none"> • Place • Duration • Verification check-list • Passed items of integration • Failed items of integration • Pending items of integration: not run, partial execution • Defects identified during integration • The applicable status is: published 	
7.	IVV Plan	<p>Elements needed to integrate, verify and validate the system.</p> <p>It may be a single documents with dedicated paragraphs or separate documents (Integration plan, verification plan, validation plan, qualification plan)</p> <p><i>IVV Plan</i> may include:</p> <ul style="list-style-type: none"> • Identifies the IVV activities regarding the System Requirements: inspection, reviews, simulation, test items • Identifies the System integration strategy regarding the System Elements Requirements and interfaces. • Environmental constraints • Requirements for IVV means • Special procedural requirements <p>The applicable statuses are: verified, published</p>	System Definition and Realization
8.	IVV Procedure	<p>Elements to execute the IVV tasks.</p> <p>It may be a single documents with dedicated paragraphs or separate documents (e.g. Integration procedure, verification procedure, validation procedure, qualification procedure)</p> <p>IVV Procedure may include:</p> <ul style="list-style-type: none"> • Purpose of the IVV procedure • Reference to the IVV plan • Defines the prerequisites • Defines procedure steps including the step number, the required action and the expected results <p>The applicable statuses are: verified, accepted, updated, and reviewed.</p>	System Definition and Realization
9.	Justification Document	<p>The justification document contains all the justifications of choices, decisions (e.g. trade-offs), results of integration verification validation.</p> <p>This document is elaborated progressively during the development of the system.</p> <p>It can be used to justify the compliance for certification or qualification.</p> <p>The applicable statuses are: initial, published</p>	System Definition and Realization
10.	Meeting Record	<p>Records the agreements established with Acquirer and/or Work Team. It may have the following characteristics:</p> <ul style="list-style-type: none"> • Purpose of meeting • Attendees • Date, place held • Reference to previous minutes • What was accomplished • Identifies issues raised • Any open issues • Agreements • Next meeting, if any. <p>The applicable status is: published.</p>	Project Management
11.	Product Acceptance Record	<p>Documents the Acquirer acceptance of the <i>Deliverables</i> of the project. It may have the following characteristics:</p> <ul style="list-style-type: none"> • Record of the receipt of the delivery • Identifies the date received • Identifies the delivered elements 	Project Management

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		<ul style="list-style-type: none"> • Records the verification of any Acquirer acceptance criteria defined • Identifies any open issues (if applicable) • Signed by receiving Acquirer <p>The applicable statuses are: approved, published</p> <p>Project Management</p>	
12.	Product	<p>A uniquely identified and consistent set of system elements including:</p> <ul style="list-style-type: none"> • <i>Stakeholders Requirements Specification System Requirements Specification</i> • <i>System Elements Requirements Specification</i> • <i>System Design Document</i> • <i>Traceability Matrices (includes Requirements traceability matrix, Requirements coverage matrix)</i> • <i>System Elements</i> • <i>System</i> • <i>Bought, built or re-used System Elements</i> • <i>IVV Plan</i> • <i>IVV Procedure</i> • <i>Verification Report</i> • <i>Validation Report</i> • <i>System Operation Guide</i> • <i>System User Manual</i> • <i>System Maintenance Document</i> 	System Definition and Realization
13.	Project Plan	<p>Presents how the project processes and activities will be executed to ensure the project's successful completion, and the quality of the deliverable system. It includes the following elements which may have the characteristics as follows:</p> <ul style="list-style-type: none"> - Reference to the SOW - <i>System Description</i> - Purpose - General Acquirer requirements - Scope description of what is included and what is not - <i>Objectives</i> of the project - <i>Deliverables</i> – list of system items to be delivered to Acquirer - <i>System Breakdown Structure</i> - <i>Tasks with leaders and contributors</i>, including verification, validation and reviews with Acquirer and Work Team, to ensure the quality of work products. <i>Tasks</i> may be represented as a Work Breakdown Structure (WBS). - <i>Estimated Duration</i> of tasks - <i>Resources</i> (humans, materials, standards, equipment and tools) including the required training, and the schedule when the <i>Resources</i> are needed. - <i>Composition of Work Team and roles</i> - <i>Schedule of the Project Tasks</i>, the expected start and completion date for each task, and the relationship and dependencies of the <i>Tasks</i>. - <i>Milestones</i> - <i>Estimated Effort and Cost</i> - <i>Risk Management Approach</i> - Identification of Project Risks - Evaluation of each risk - Assignment of a priority to each risk - Treatment of risks - Periodically monitor risks for change - Periodically reviewing risk information on the risks identified - <i>Configuration Management Strategy</i> 	Project Management

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		<ul style="list-style-type: none"> - System configuration management tool and mechanisms identified - Version identification and control defined - Backup and recovery mechanisms defined - Storage, handling and delivery (including archival and retrieval) mechanisms specified - <i>Change control process</i> to manage the changes based on impact studies using traceability and change control boards. - <i>Delivery Instructions</i> - Elements required for system release identified (i.e. hardware, software, documentation) - Delivery requirements - Sequential ordering of <i>Tasks</i> to be performed - Applicable releases identified - Identifies all delivered <i>System Elements</i> with version information - Identifies any necessary backup and recovery procedures - <i>Disposal Management Approach</i> - Defines schedules, actions and resources - Defines how to transform the system into, or retain it in, a socially and physically acceptable state <p>The applicable statuses are: verified, accepted, updated and reviewed.</p>	
14.	Project Repository	<p>Container to store project work products and deliveries. It may have the following characteristics:</p> <ul style="list-style-type: none"> • Stores project work products • Stores released <i>Deliverables</i> products • Storage and retrieval capabilities • Ability to browse content • Listing of contents with description of attributes • Sharing and transfer of work products between affected groups • Effective controls over access • Maintain work products descriptions • Recovery of archive versions of work products • Ability to report work products status • Changes to work products are tracked to <i>Change Requests</i> <p>The applicable statuses are: established, recovered and updated.</p>	Project Management
15.	Project Repository Backup	Repository used to backup the <i>Project Repository</i> and, if necessary, to recover the information.	Project Management
16.	Progress Status Record	<p>Records the status of the project against the <i>Project Plan</i>. It may have the following characteristics:</p> <ul style="list-style-type: none"> • Status of actual <i>Tasks</i> against planned <i>Tasks</i> • Status of actual results against established <i>Objectives/ goals</i> • Status of actual resource allocation against planned <i>Resources</i> • Status of actual cost against budget estimates • Status of actual time against planned schedule • Status of actual risk against previously identified • Record of any deviations from planned <i>Tasks</i> and reason why. <p>The applicable status is: evaluated.</p>	Project Management
17.	Purchase Order	<p>Defines the artefact to be purchased. It may have the following characteristics:</p> <ul style="list-style-type: none"> • Name and address of supplier • Description of the item purchased • Agreed price • Quantity • Delivery date <p>The applicable statuses are: initiated, approved.</p>	
18.	Stakeholders	Defines the acquirer and other stakeholder's requirements.	System Definition and

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	Requirements Specifications	<p>It may be in a single document with all stakeholders explicitly identified or in separate documents.</p> <p>It may have the following characteristics:</p> <ul style="list-style-type: none"> • Introduction – general description of <i>the main goals; needs and expectations</i> • Requirements description: <ul style="list-style-type: none"> - Regulation - Capabilities - Performances - Scenarios, * Concepts of operations - User interface - Interfaces - Reliability - Maintenance - Interoperability - Constraints <p>The applicable statuses are: initiated, approved, baselined</p>	Realization
19.	Statement of Work (SOW)	<p>Description of work to be done related to <i>System</i> development.</p> <p>It may Include:</p> <ul style="list-style-type: none"> - <i>System Description (Needs and expectations)</i> - Purpose - Acquirer and stakeholders requirements - Constraints (regulation, imposed solutions...) - <i>Scope</i> description of what is included and what is not - <i>Objectives</i> of the project - <i>Deliverables</i> list of products to be delivered to Acquirer <p>A SOW could be part of a contract between the Acquirer and the Supplier</p> <p>The applicable status is: reviewed.</p> <p>Project Management Validation Plan, Safety, Security, and Mission Assurance</p> <ul style="list-style-type: none"> • Acronyms list, project organization, project WBS, project schedule, document tree <p>The applicable statuses are: verified, accepted, reviewed</p>	Project Management
20.	System	<p>Combination of interacting elements organized to achieve one or more stated purposes.</p> <p>The applicable statuses are: verified, validated.</p>	System Definition and Realization
21.	Systems Engineering Management Plan (SEMP)	<p>Identifies and describes the project organization, roles and responsibilities, overall tasks, and engineering management planning required to control the design, development, fabrication, and tests associated with the Project.</p> <p>It may have the following Characteristics:</p> <ul style="list-style-type: none"> • Introduction, Purpose, Scope • Company and Government Documents • Technical Project Planning and Control • Project Organization, Responsibility and Authority, Standards, Procedures, and Training, Work Breakdown Structures, Technical Design Verification and Validation, Change Control Procedures, Systems Integration, Interface Control, Project Schedule and Milestones, Project Reviews, Technical Performance Management (TPM), Technical Communication, Mission Assurance, Project Risk Analysis • Systems Engineering Process • Project Requirements Analysis and Definition, Functional Analysis, Requirement Allocation, Trade-off Studies, Design Optimization/Effectiveness Compatibility, Lessons Learned, 	System Definition and Realization

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		<p>Synthesis, Logistics Support, Producibility Analysis, Documentation, Systems Engineering Tools, Information Technology Systems Security,</p> <ul style="list-style-type: none"> • Integration of Speciality Engineering Effort • Speciality Engineering, Integration Design, Integrated Validation Plan, Safety, Security, and Mission Assurance • Acronyms list, project organization, project WBS, project schedule, document tree <p>The applicable statuses are: verified, accepted, reviewed</p>	
22.	System Design Document	<p>Textual and/or graphical information, model on the <i>System</i> structure (solution). This structure may include the following parts:</p> <p>Functional Architecture:</p> <ul style="list-style-type: none"> • Identifies the required <i>Internal Functions</i> • Identifies the relationship between <i>Internal Functions</i> • Consideration is given to any required: <ul style="list-style-type: none"> - <i>System</i> performance characteristics - Functional and human interfaces - Security characteristics <p>Physical Architecture:</p> <ul style="list-style-type: none"> • Provides hardware design • Identifies the required <i>Physical Elements</i> • Identifies the allocation of <i>Internal Functions</i> to <i>Physical Elements</i> • Provides format of input / output interfaces: physical interfaces, functional data through physical interfaces. • Defines the format of required data structures <p>The applicable statuses are: verified and baselined.</p>	System Definition and Realization
23.	System Element	<p>A product, that is part of a system, and that can be implemented to fulfil specified requirements.</p> <p>Examples: hardware, hardware with software, software, data, humans, processes (e.g. processes for providing service to users), procedures (e.g. operator instructions), facilities, materials, and naturally occurring entities (e.g. water, organisms, minerals), or any combination</p>	System Definition and Realization
24.	System Elements Requirements Specifications	<p>Defines the system elements requirements that satisfy the system requirements according to the system functional and physical architecture.</p> <p>Interfaces resulting from the system functional and physical architecture may be defined within the <i>System Elements Requirements Specifications</i> or in separate document.</p> <p>Each requirement is uniquely identified and is described with the SMART criteria.</p> <p>The applicable statuses are: initiated, verified, validated and baselined.</p>	
25.	System Maintenance Document	<p>Defines the requirements and operations to maintain the system.</p> <p>It may have the following characteristics:</p> <ul style="list-style-type: none"> • Maintenance Strategy - Accounts for the system's technical availability, replacements for system elements and logistical support, maintenance personnel training and staff requirements 	System Definition and Realization

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		<ul style="list-style-type: none"> • Maintenance Enabling System Requirements – Requirements for any system needed to enable maintenance of the system-of interest need to be developed • Maintenance Constraints on Design – Any constraints on the design arising from the maintenance strategy • Maintenance Procedure • Maintenance Report – Including documentation of the maintenance activity results, reporting of failures and recommendations for action, and failure and lifetime performance data. This report also documents any required procedure or system changes that should be accomplished as part of on-going configuration management activities. <p>The applicable statuses are: preliminary, verified, validated</p>	
26.	System Operation Guide	<p>Contains the necessary information to install and manage the <i>System</i>.</p> <p>It may have the following characteristics:</p> <ul style="list-style-type: none"> • Criteria for operational use • A description of how to operate the product including: <ul style="list-style-type: none"> - operational environment required - supporting tools and material (e.g. system user manuals) required - possible safety warnings - start-up preparations and sequence - frequently asked questions (FAQ) - sources of further information and help to operate the product • Certification and safety approvals • Warranty and replacement instructions • It should be written in terms that the personnel responsible for the operation can understand. <p>The applicable statuses are: preliminary, verified and baselined.</p>	System Definition and Realization
27.	System Requirements Specifications	<p>Defines the system requirements that satisfy the stakeholders' requirements. It may have the following characteristics:</p> <ul style="list-style-type: none"> • Introduction – general description of the <i>System</i> and its use within the <i>Scope</i> of the Acquirer business; • Requirements description: <ul style="list-style-type: none"> - Functionality – established needs to be satisfied by the <i>System</i> when it is used in specific conditions. Functionality must be adequate, accurate and safe - User interface – definition of those user interface characteristics that allow to understand and learn the <i>system</i> easily so the user be able to perform his/her <i>Tasks</i> efficiently including the interface exemplar description - External interfaces – definition of interfaces with other system, software or hardware - Reliability – specification of the system execution level concerning the maturity, fault tolerance and recovery - Efficiency – specification of the system execution level concerning the time and use of the <i>Resources</i> - Maintainability – degree of effectiveness and efficiency with which a product or system can be modified by the intended maintainers. - Portability – description of the <i>System</i> characteristics that allow its transfer from one place to other 	System Definition and Realization

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		<ul style="list-style-type: none"> - Design and construction limitations/constraints –Interoperability – capability for two or more systems or <i>System Elements</i> be able to change information each other and use it - Reusability – feature of any product/sub-product, or a part of it, so that it can be used by several users as an end product, in the own system development, or in the execution of other system products - Legal and regulative – needs imposed by laws, regulations, etc. <p>Each requirement is uniquely identified and is described with the SMART criteria.</p> <p>The applicable statuses are: initiated, verified, validated and baselined.</p>	
28.	System Training Specifications	<p>Describes the requirements and operation to train the users, maintainers, and support personnel of a system to accomplish required tasks at any point in the system life cycle (transition, use, maintenance, disposal).</p> <p>The applicable statuses are: initiated, verified, validated and baselined.</p>	System Definition and Realization
29.	System User Manual	<p>Describes the way of using the System based on the user interface. It may have the following characteristics:</p> <ul style="list-style-type: none"> • User procedures for performing specified Tasks using the System • Installation and de-installation procedures • Brief description of the intended use of the System: a user-oriented document that describes a system's operational characteristics from the end user's viewpoint (the concept of operations) • The supplied and required Resources • Needed operational environment • Availability of problem reporting and assistance • Procedures to access and exit the System • Lists and explains System commands and system-provided messages to the user • As appropriate for the identified risk, it includes warnings, cautions, and notes, with corrections • It includes troubleshooting and error correction procedures. <p>It is written in terms understandable by users.</p> <p>The applicable statuses are: preliminary, verified and baselined.</p>	System Definition and Realization
30.	Traceability Matrix	<p>Documents the relationship between engineering and IVV artefacts according to the data model.</p> <p>It include:</p> <ul style="list-style-type: none"> • Requirements traceability matrix • Requirements coverage matrix <p>The applicable statuses are: verified, baselined and updated.</p>	System Definition and Realization
31.	Validation Report	<p>Documents the validation execution.</p> <p>It may include the record of:</p> <ul style="list-style-type: none"> • Reference to the related IVV procedures • Date • Place • Duration 	System Definition and Realization

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		<ul style="list-style-type: none">• Validation check-list• Passed items of validation• Failed items of validation• Pending items of validation: not run, partial execution• Defects identified during validation <p>The applicable status is: published</p>	
32.	Verification Report	<p>Documents the verification execution.</p> <p>It may include the record of:</p> <ul style="list-style-type: none">• Reference to the related IVV procedures• Date• Place• Duration• Verification check-list• Passed items of verification• Failed items of verification• Pending items of verification: not run, partial execution• Defects identified during verification <p>The applicable status is: published</p>	System Definition and Realization

Version History

Date	Version	Description	Author
24-Jan-17	0.01	Initial Draft Release for IW17 SE Framework for VSE in the Medical Technology Space	Angela Robinson