Thinking from Process Results

Process Insights 2026-03

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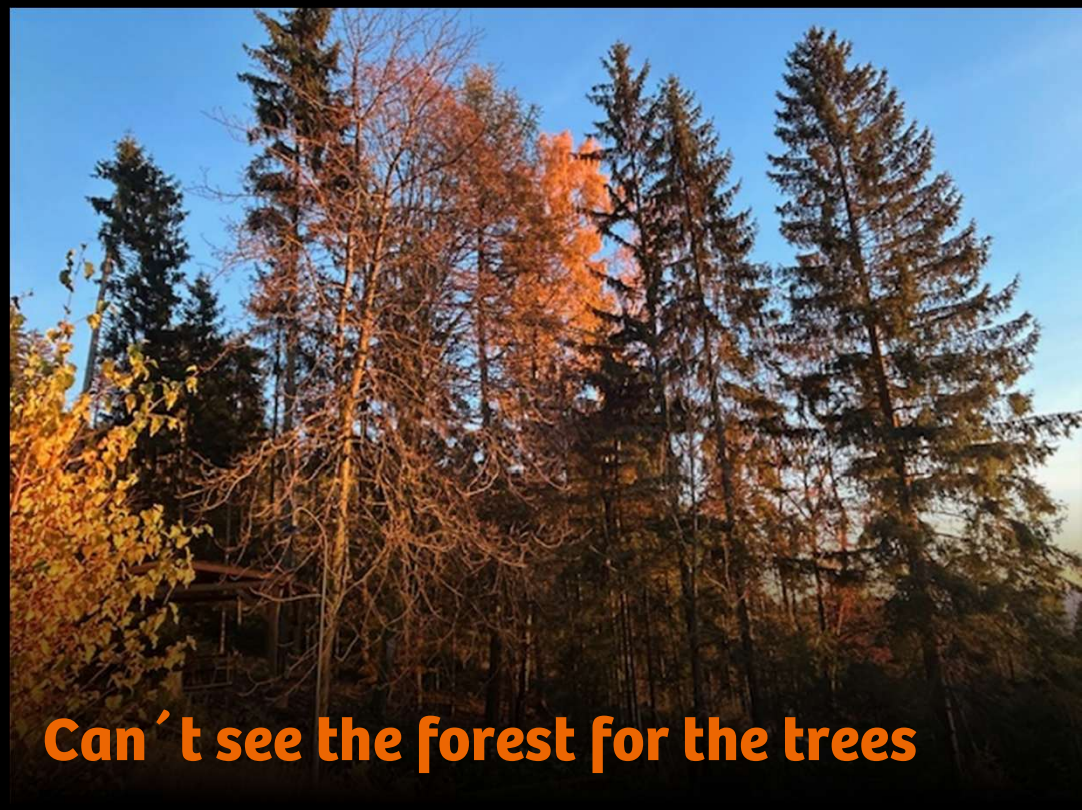
UL Solutions SIS, Dr. Oliver Hammrich

Content



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Content

Do complex products need complex processes?

YES!

Each new megatrend follows its predecessor more quickly than the previous one:

Steam Engine – Computer – Internet/Digitization – Electrification – **AI** – VR/AR – Warp Drive – etc.

First Law of Systems Engineering:
Every new technology brings new engineering domains and compliance standards.

→ more engineering processes
→ more interfaces
→ more compliance mappings
→ more tailoring options

Example Standard: UL 3115
“Outline of Investigation for Safety of AI-Based Products” says:

“Requirements (R42) include the following:

The AI system shall have user interfaces (UIs) that enable control and potential overriding of AI decisions and document them.

These UIs should be:
1) Intuitive and User-Friendly […]
2) Granular and Contextual […]
3) Secure and Verifiable […]”

Complexity in Compliance

We have known how to achieve compliance with **process requirements** since CMM and SPICE. But how can you ensure that your product meets the **product requirements**?

It is not only about carrying out Activities or having a Work Product; it is about what is inside your Work Products.

We need to map these product requirements to Work Product **content:** descriptions, templates, checklists, quality levels, or anything else defining content.

New technology standards require:
More focus on Work Product's content

How to Reduce Complexity?

Second Law of Systems Engineering:

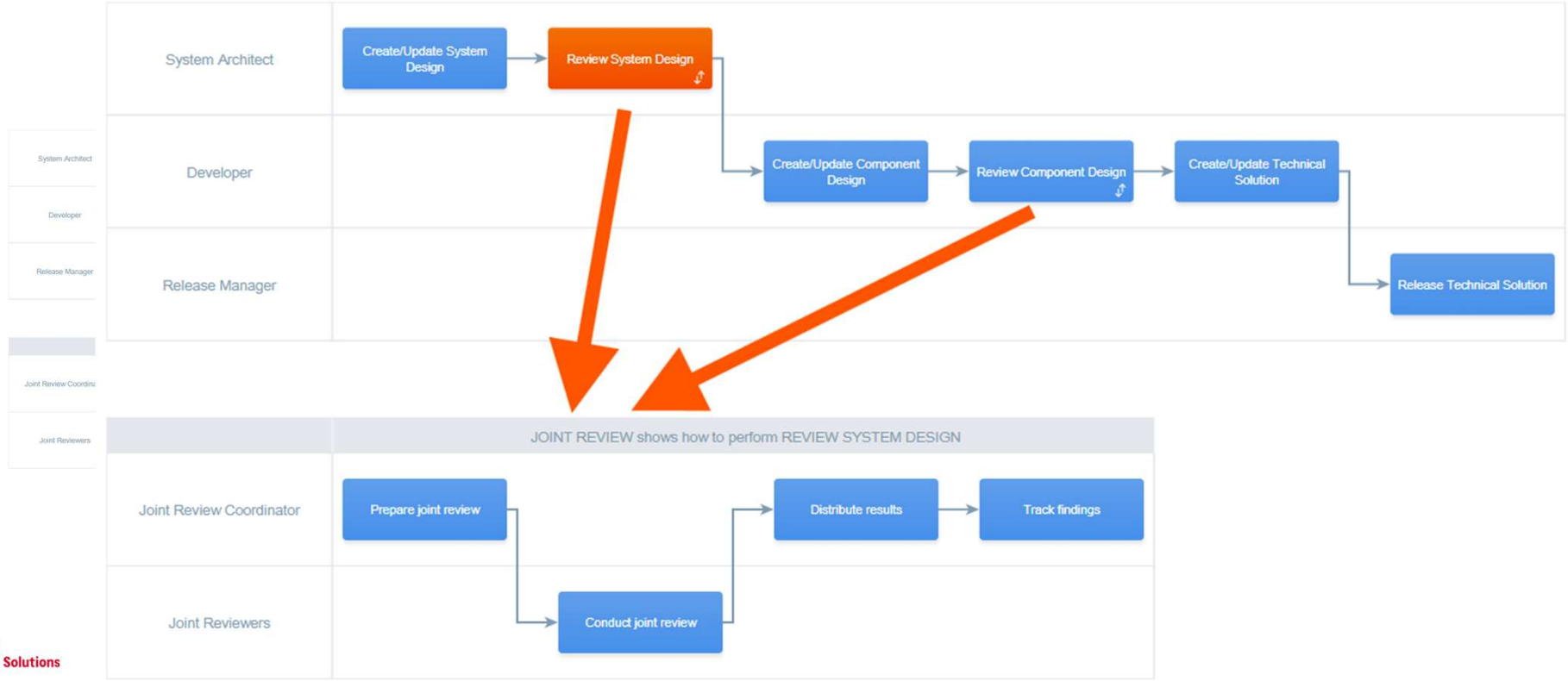
Complexity cannot be reduced.

But it needs to be managed to avoid emergent behavior, chaos, and the heat death of the universe.

How to ~~Reduce~~ Manage Complexity?

What we already have (procedural programming):
Find patterns of Activities and reuse like a subroutine!
(Stages widget “Find Details In”)

What we could strive for (object-oriented programming):
Find patterns (Artifact-based) in the **content** of Work Products and inherit like a superclass.



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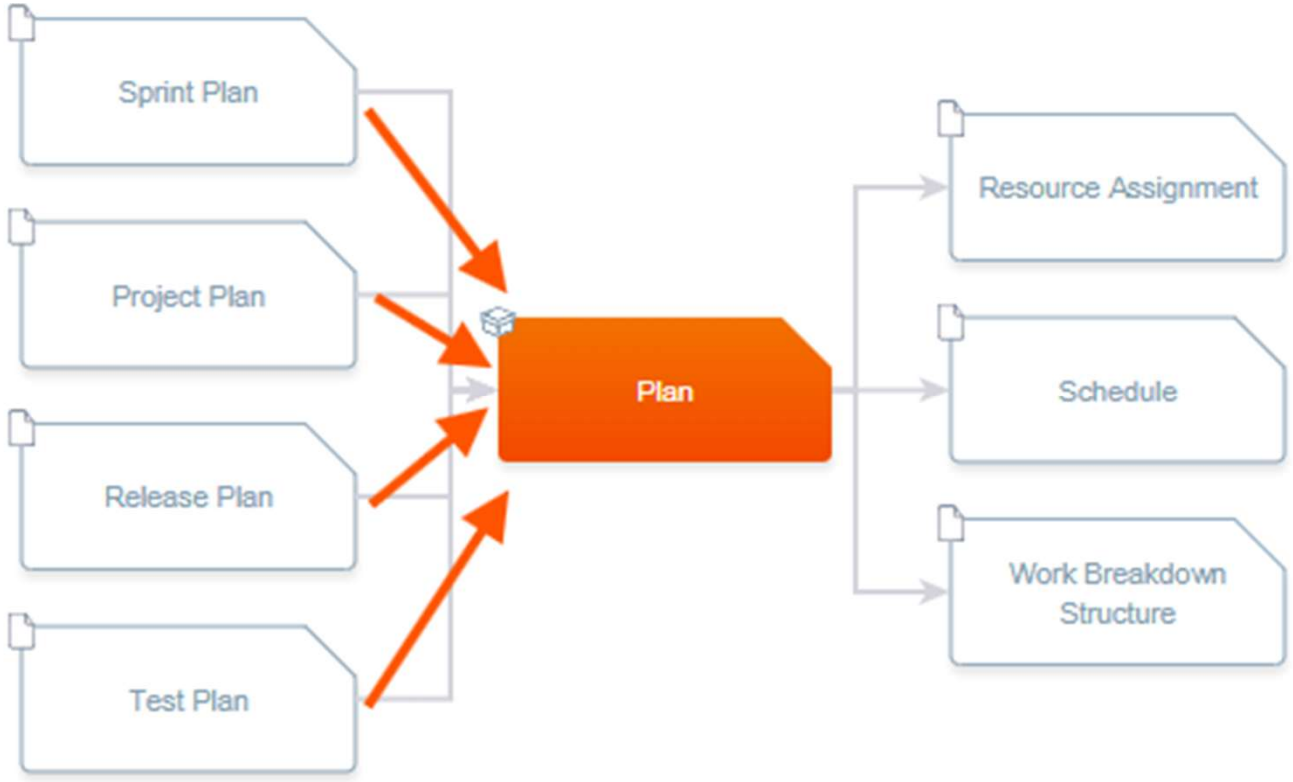

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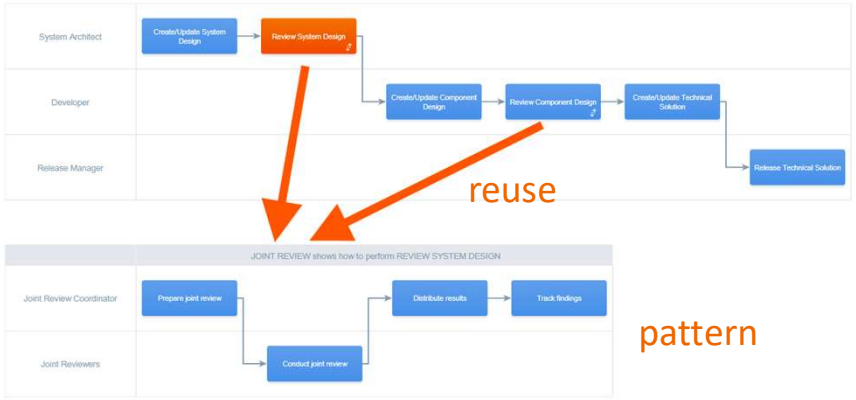

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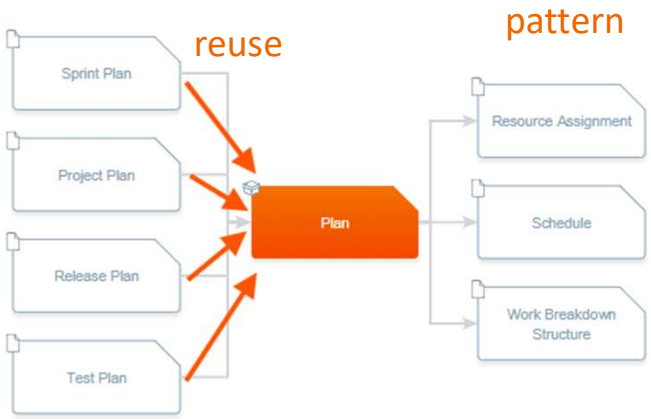
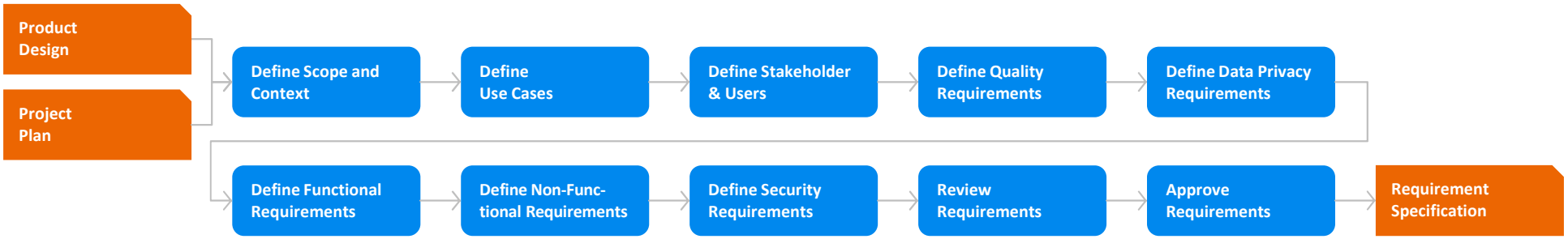
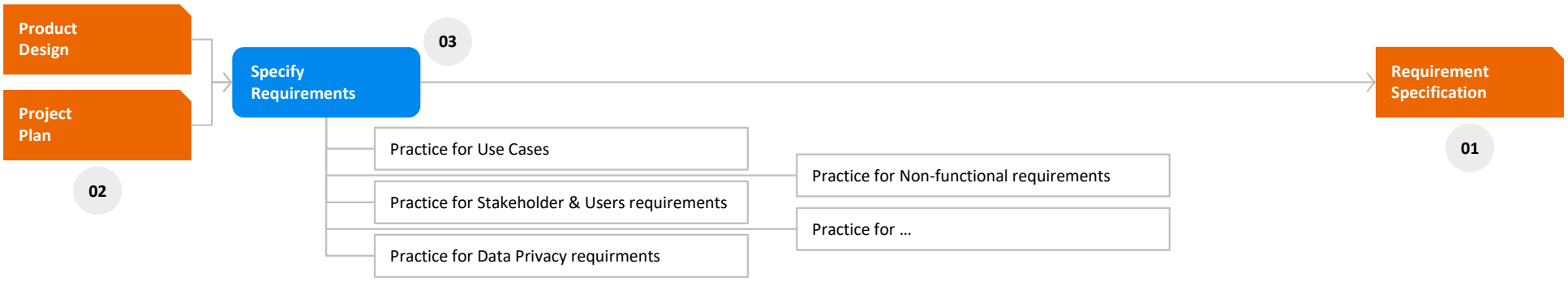


Why are many process models so complex and detailed?
Thinking from doing

We are often thinking about what we are doing within a process



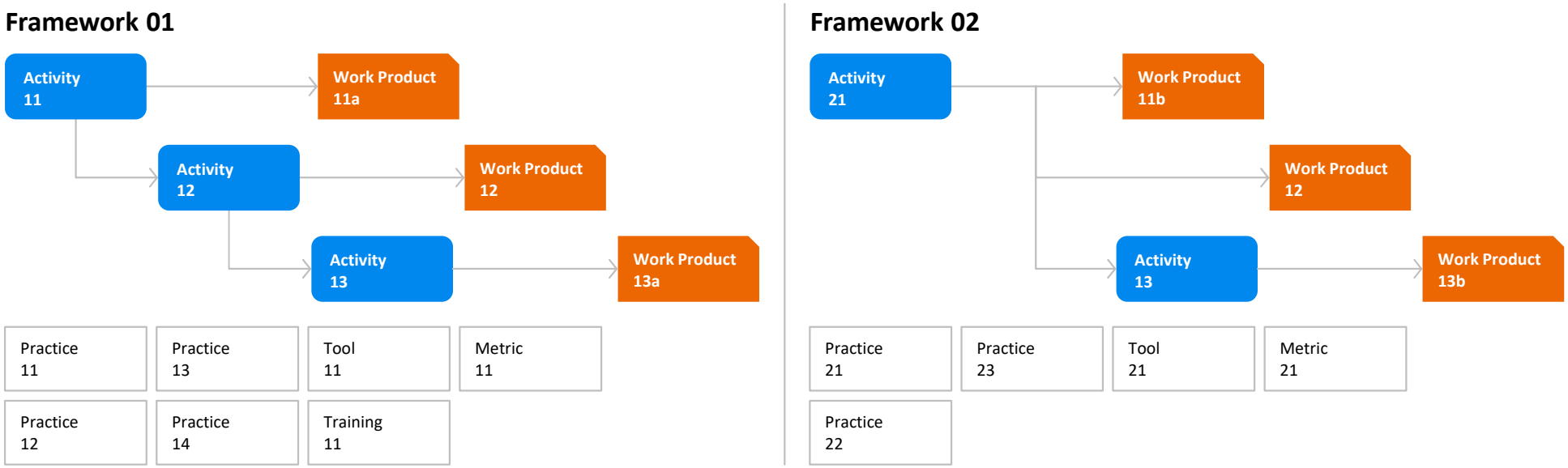
Focussing on **Process Results** helps for creating a slim process structure.



Why are many process models so complex and detailed?

Harmonization of processes

Parts of organizations are merged into one process framework/quality management system, but both parts have an own process → How to harmonize processes?



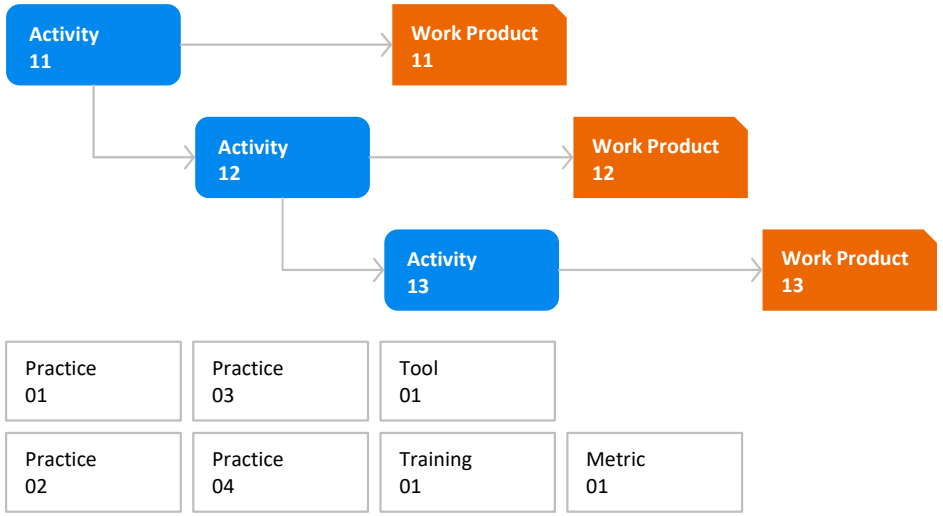
Focus on harmonization of **Process Results,** because the **WHAT is relevant for evidence.** Harmonization or merge of activities and guidances note necessary (or can be done later), because the HOW is not relevant for evidence.

Content

Why is finding the correct answers in audits sometimes difficult?

Auditors are only interested in evidence about what he/she is asking for.
He/she is not interested in what we are doing all day.

Framework 01



It is always better to define the **Process Results** with clear content, where the requested evidence is given. This can easily be provided during audits.

Typical auditor question:

How did you accept the delivery from supplier?

→ The auditor doesn´t want to know, what you **DID,** but he wants to see what you´ve **DOCUMENTED!**

Content

Definition of a Work Product

Relevant information

Define content:

A	Definition
B	Detailed content information, if possible, with hints for completion

Provide template or tool

Provide checklist, if relevant

Provide information about review and archiving rules

Example “Verification Test Case Result”

Definition

The Verification Test Case Result documents the results of the Verification Test Case execution.

Improved Example “Verification Test Case Result”

Definition

The Verification Test Case Result documents the results of the Verification Test Case execution.

Detailed content information

Verification Test Case

<Give the test case identifier and version of the test case which was tested.>

Test Performed by

<Give the name of the tester(s) who executed the test case.>

Test Date

<Give the date when the test case was executed, e.g., test start date and test end date.>

Test Object

<Give the identifier and version of the test object which was tested.>

Test Environment

<Give the identifier and version of the test environment which was used for the test. >

Monitoring/Measuring Equipment (actual) (if applicable)

<Give the identifier (e.g., serial number) of the monitoring/ measuring equipment(s) which was used and the date of calibration (e.g., end date of calibration or date of next calibration).>

Test Result

<Give the actual test result of the test case execution whether passed or failed, according to the actions and expected results specified for the test case. Give the actual result (e.g., screenshot, measured values) as specified for the test case. In case of failed test case execution give the change request identifier. If applicable, state the results of verification with interfaces to other devices or accessories. In case the tests are executed by an external test laboratory, refer to the external test report.>

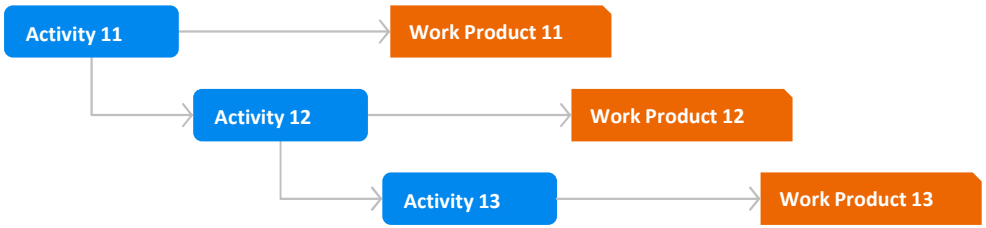
Comments (if applicable)

<Enter comments if needed to explain the test result, e.g., any deviations from the required test environment or actions/expected results defined for the test case with a rationale why the test result is passed.>

Why do process users often not know what to deliver, when, and in which quality?

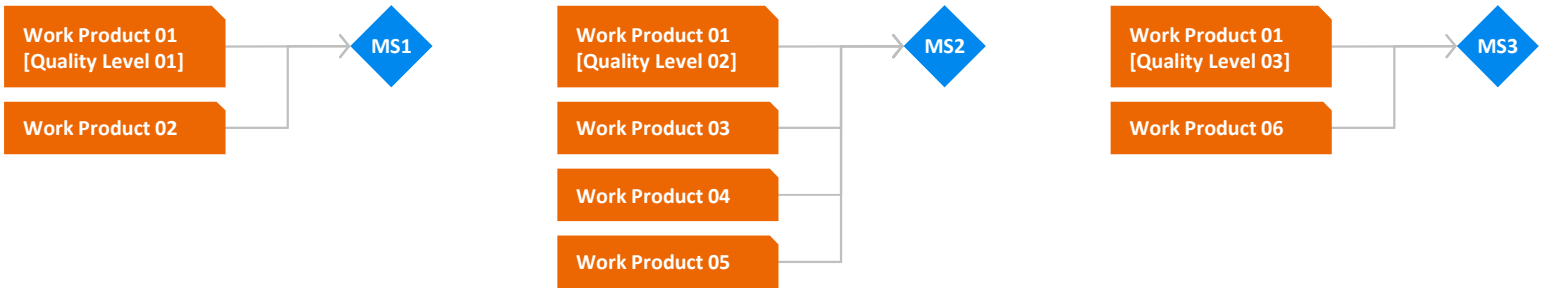
A Requested content is sometimes spread over activities, guidances and work products

B Tools or templates are exchangeable, the process definition is input for both and shall be stable



Practice 01	Practice 03	Tool 01	
Practice 02	Practice 04	Training 01	Metric 01

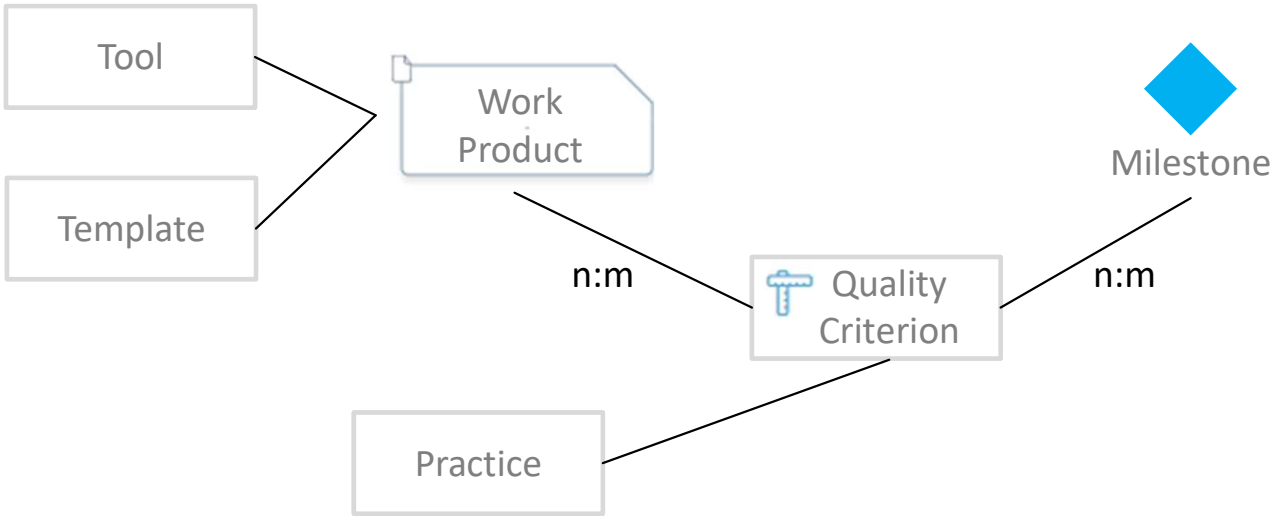
Summarize the process requirements in the **Process Results** with a clear definition of content and quality



With “lesser” Activities – how shall I know what to do and how?

First Law of System Dynamics:

In a closed process, information is conserved.

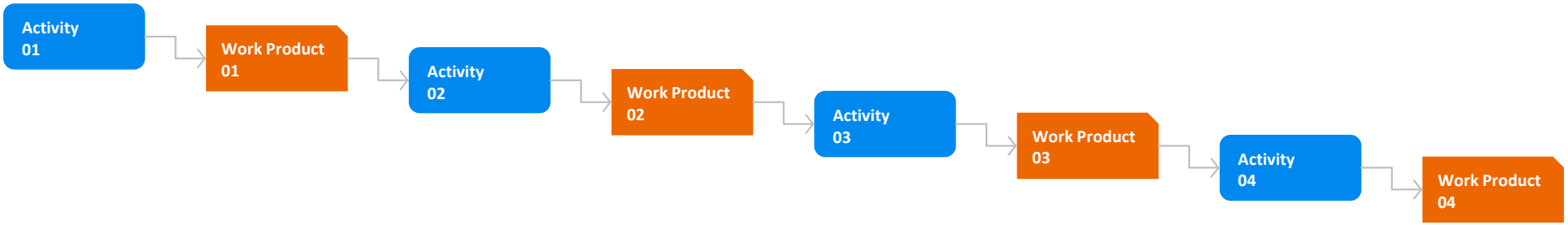


→ Side effect: reusing Activities in all Phases is now possible, because Phase-specific info is now in Quality Criteria

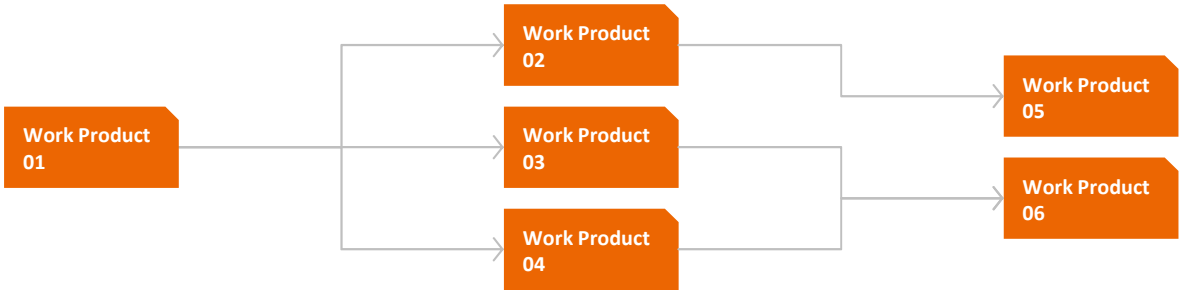
Content

Why do users feel hindered by processes, especially when working with agile methods?

An activity flow puts waterfall-thinking into our mind



Dependencies of Work Products clearly define the sequences of approvals, but parallel work can easier be planned iteratively with focussing on **Process Results.**



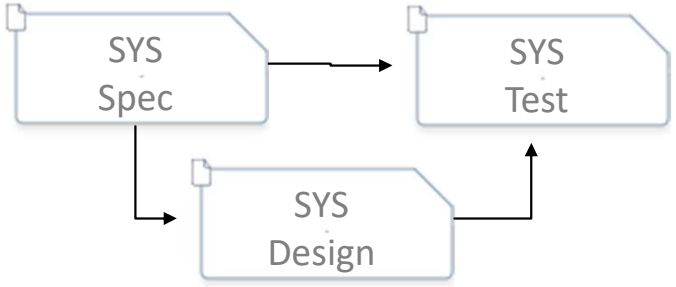
Are engineering workflows iterative and incremental?

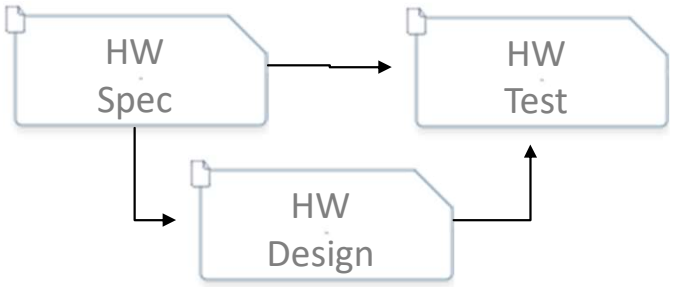
No, they are not!

But process execution should be!

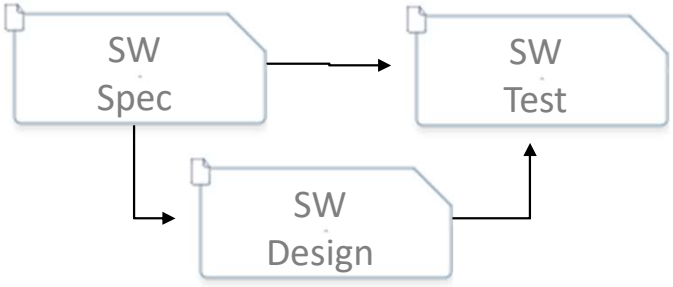
Agile process execution: iterative and incremental!

System Engineering Workflow



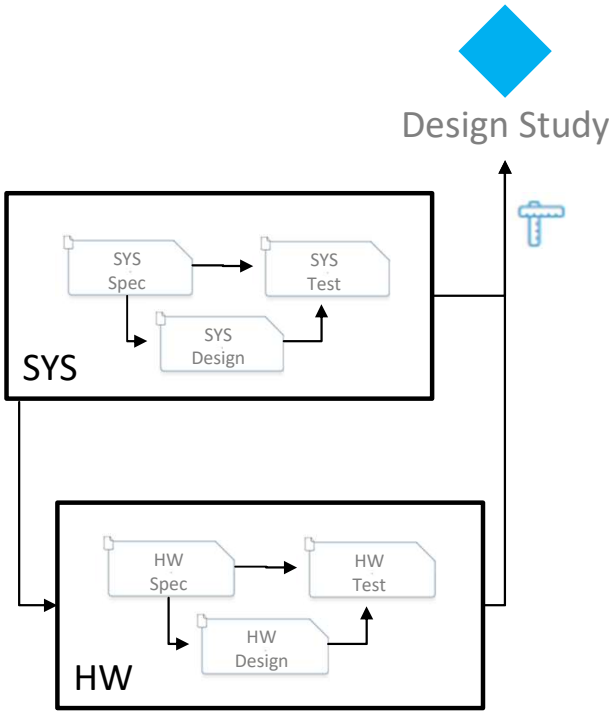


Hardware Engineering Workflow



Software Engineering Workflow

Agile process execution: iterative and incremental!



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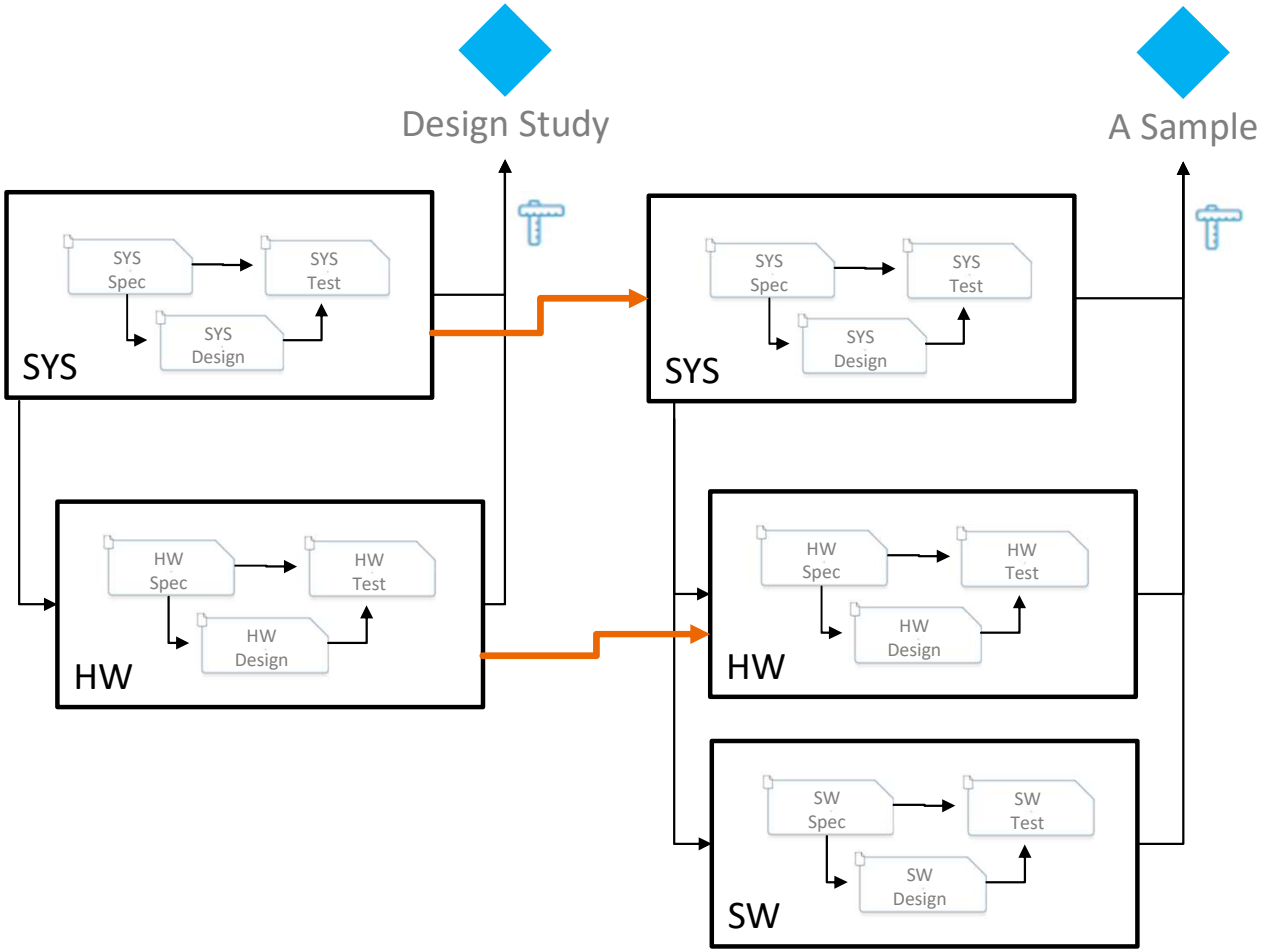

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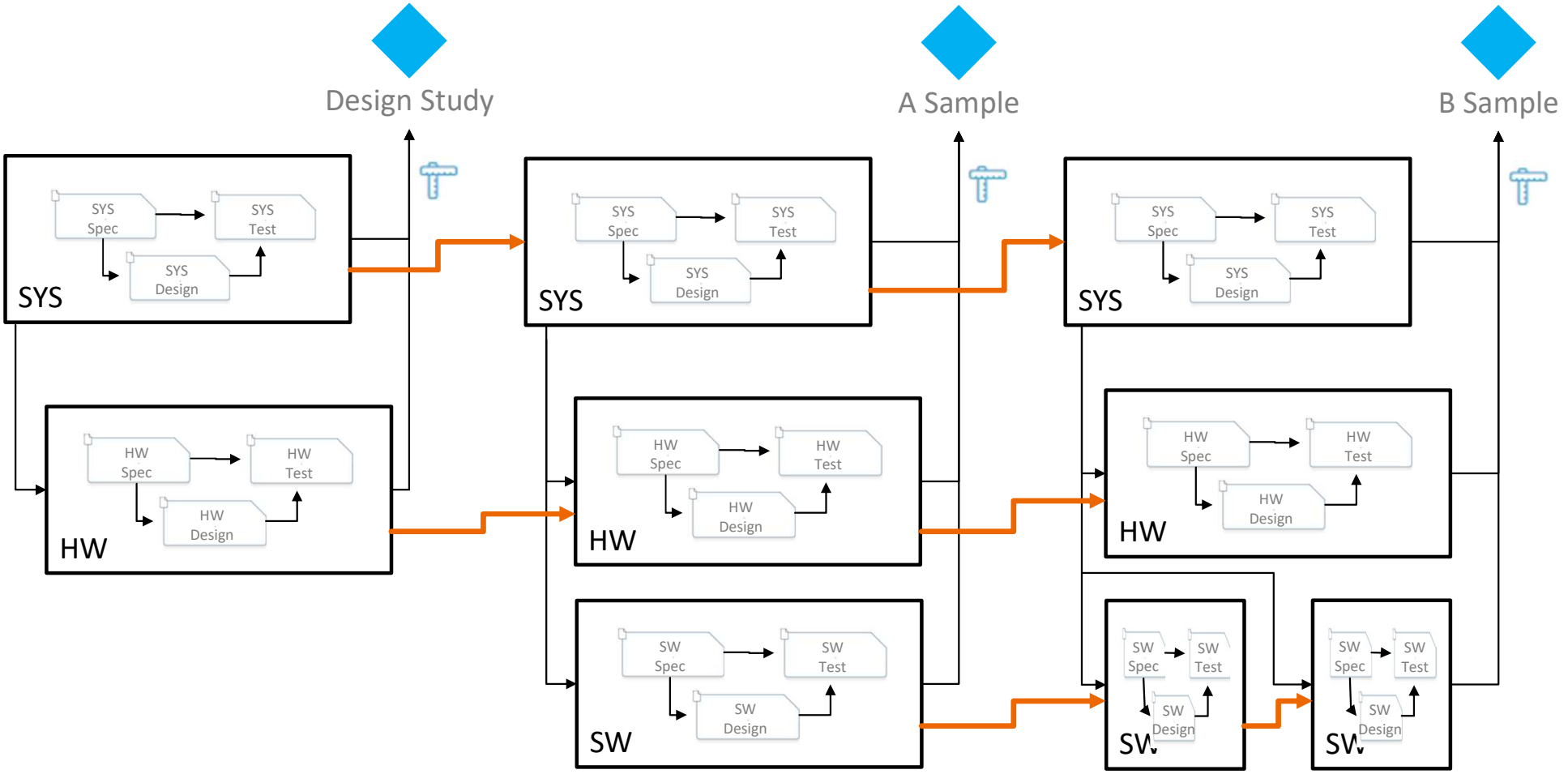

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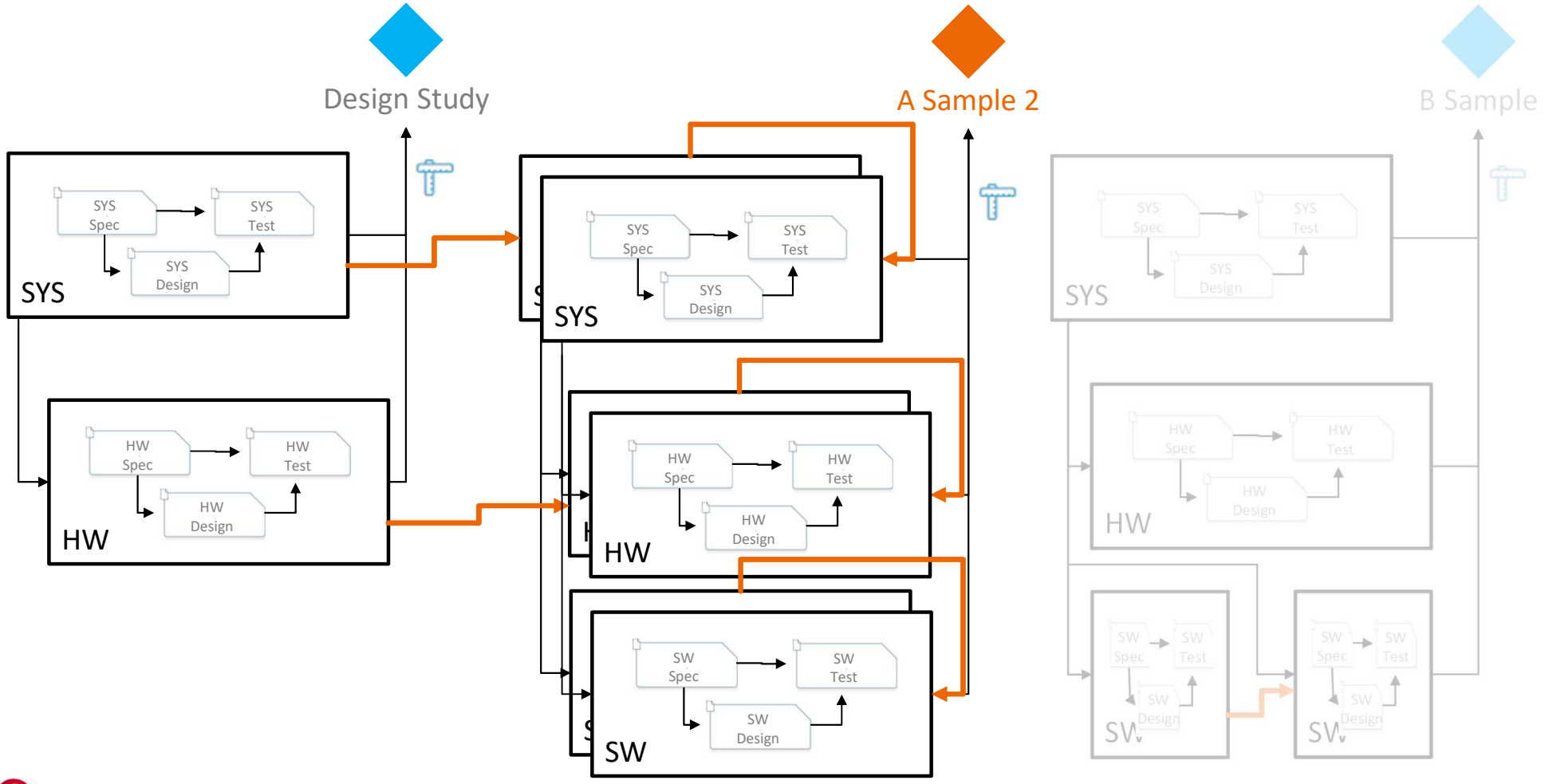

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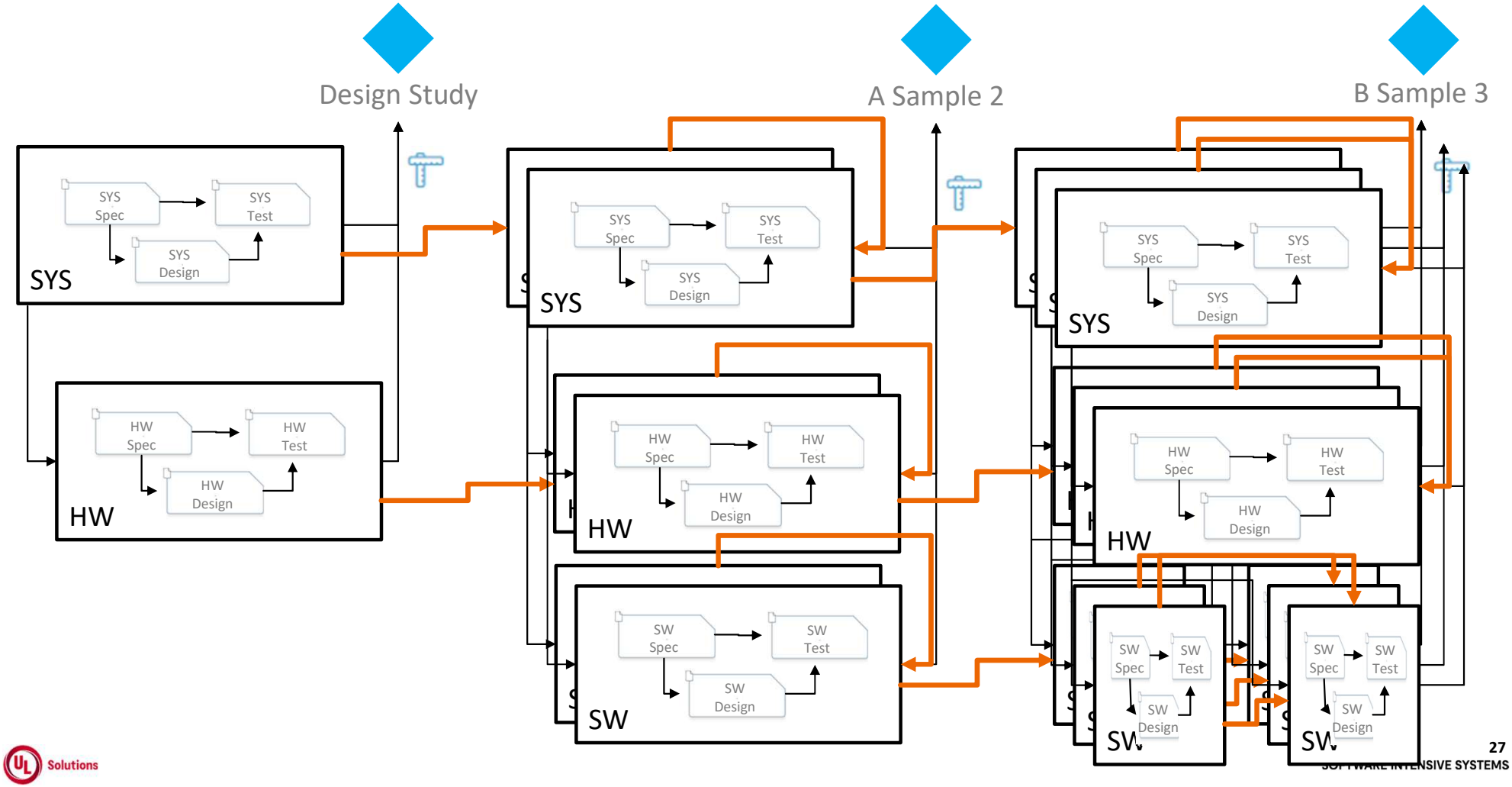


Content

Root Cause

SIEMENS Healthineers

One underlying cause of these symptomatic problems is that we **focus too much on doing, on activities.** This way of thinking is found in all industries alike.

This can be met by **focusing** more on **process results** during **process modeling** and **process visualization.**

Source picture: private

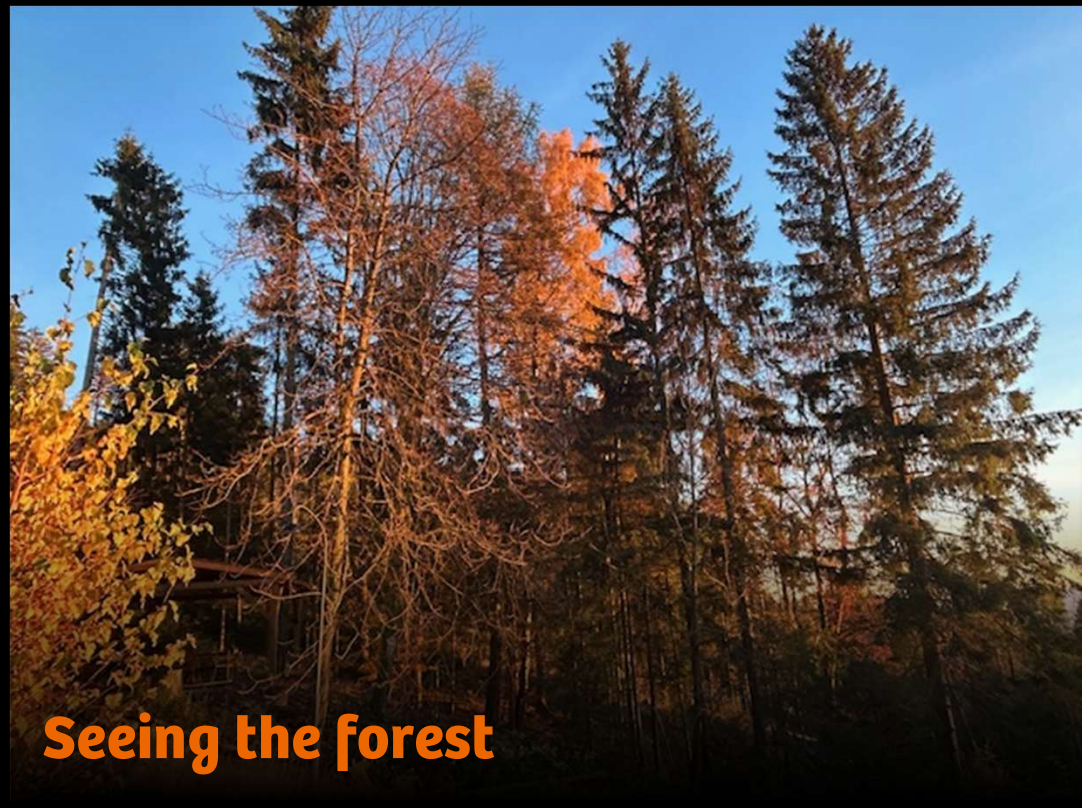
Outlook

Modeling

Process modeling consequently with focus
on work products is a task of process experts → training

Process Visualization

- Metamodell adaptions
- Dependency Plans of Work Products
- Visualization of Role – Work Product – Milestone
  (who – what – until when)
- Further ideas – You are welcome
  to our “Round Table”



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Thank you
for your enthusiasm!

Siemens Healthineers

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