

FOR VICE OR VIRTUE

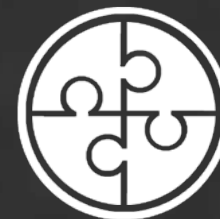
- DIGITAL VERIFICATION AND VALIDATION ACCORDING TO
ISO-15288 -



Jose Pereira

The REUSE Company
Consulting Engineer

Jose.pereira@reusecompany.com



THE
REUSE
COMPANY

INTRO TO PRESENTER ▶



- **INCOSE ASEP**
- **MAIN CONTRIBUTOR TO THE INCOSE GUIDE TO WRITING REQUIREMENTS**
- **SALES & CONSULTING REPRESENTATIVE UNDER CSEP & ESEP**
- **FIRST AUTHOR OF THE *"APPLYING THE KNOWLEDGE CENTRIC SYSTEMS ENGINEERING METHODOLOGY TO A PRACTICAL CASE"***

THE REUSE COMPANY

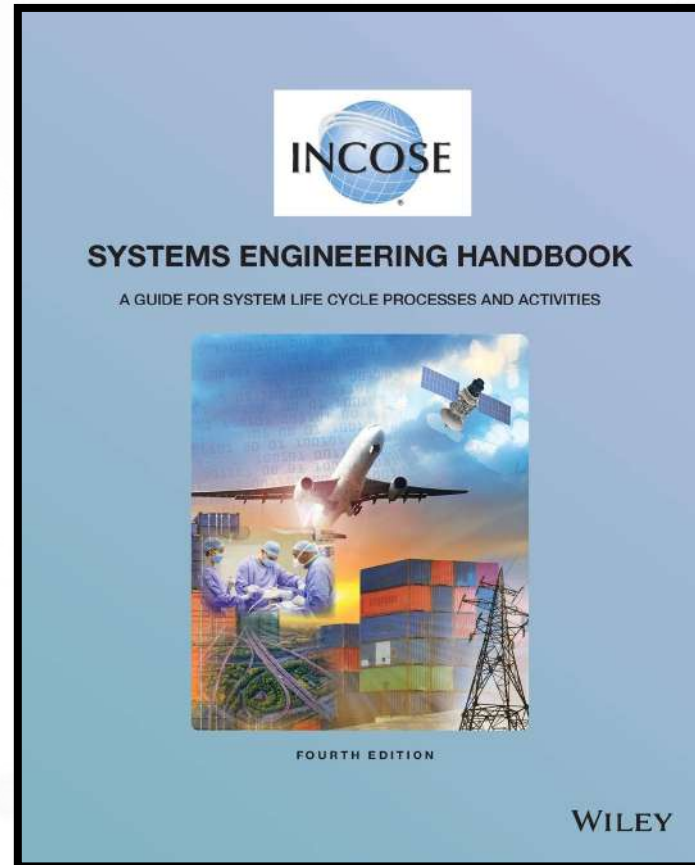
Is a tool vendor specialized in the application of
SEMANTIC TECHNOLOGIES and
ARTIFICIAL INTELLIGENCE to improve the
digitalization of the Systems Engineering life cycle.



CHAPTER 00

INTRO TO V&V

VERIFICATION AND VALIDATION PROCESSES WITHIN THE ISO 15288



KEY CONCEPTS: LIFE CYCLE PROCESSES

TECHNICAL PROCESSES	
<i>Business or mission analysis process</i>	<i>Integration process</i>
<i>Stakeholder needs and requirements definition process</i>	<i>Verification process</i>
<i>System requirements definition process</i>	<i>Transition process</i>
<i>Architecture definition process</i>	<i>Validation process</i>
<i>Design definition process</i>	<i>Operation process</i>
<i>System analysis process</i>	<i>Maintenance process</i>
<i>Implementation process</i>	<i>Disposal process</i>

ORGANIZATIONAL PROJECT-ENABLING PROCESSES
<i>Life cycle model management process</i>
<i>Infrastructure management process</i>
<i>Portfolio management process</i>
<i>Human resource management process</i>
<i>Quality management process</i>
<i>Knowledge management process</i>

AGREEMENT PROCESSES
<i>Acquisition Process</i>
<i>Supply Process</i>

TECHNICAL MANAGEMENT PROCESSES
<i>Project planning process</i>
<i>Project assessment and control process</i>
<i>Decision management process</i>
<i>Risk management process</i>
<i>Configuration management process</i>
<i>Information management process</i>
<i>Measurement process</i>
<i>Quality assurance process</i>

ISO 15288: INPUTS, PROCESSES & OUTPUTS

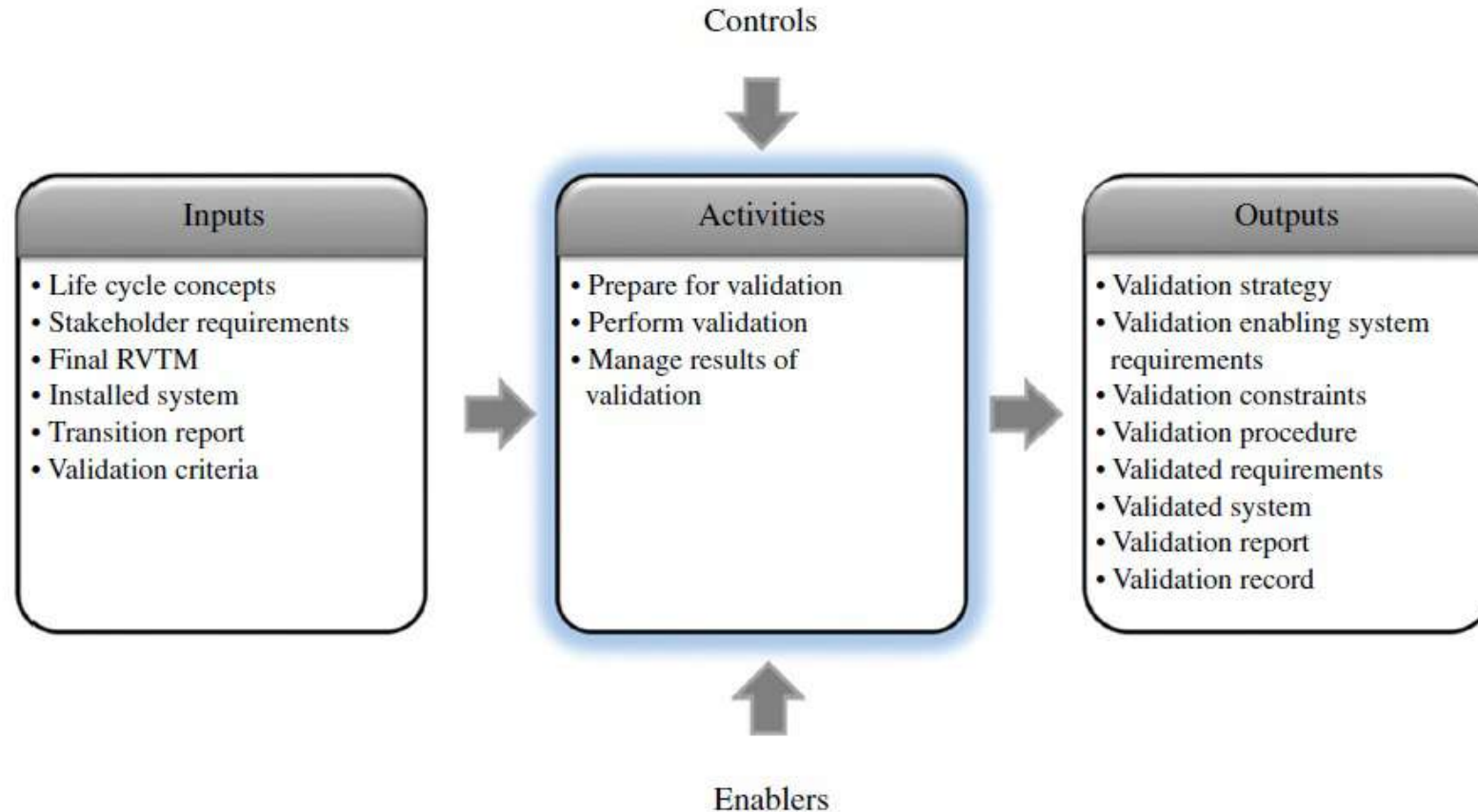
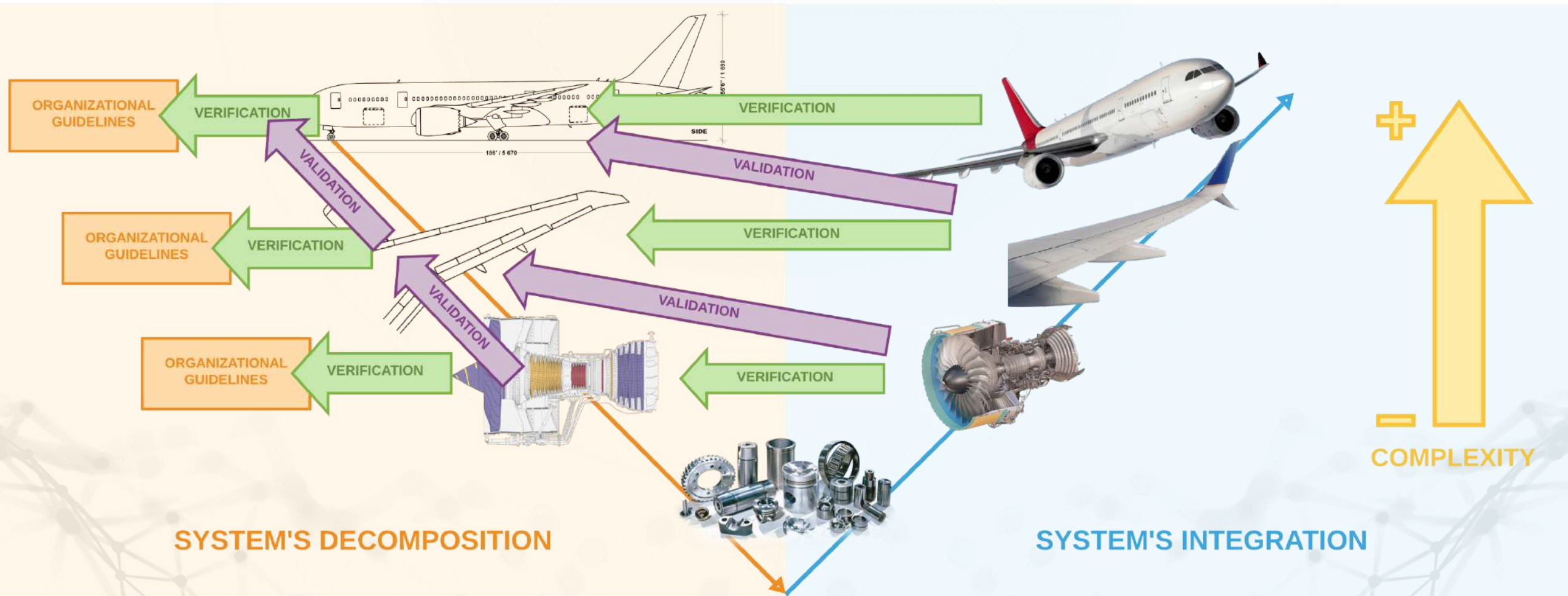
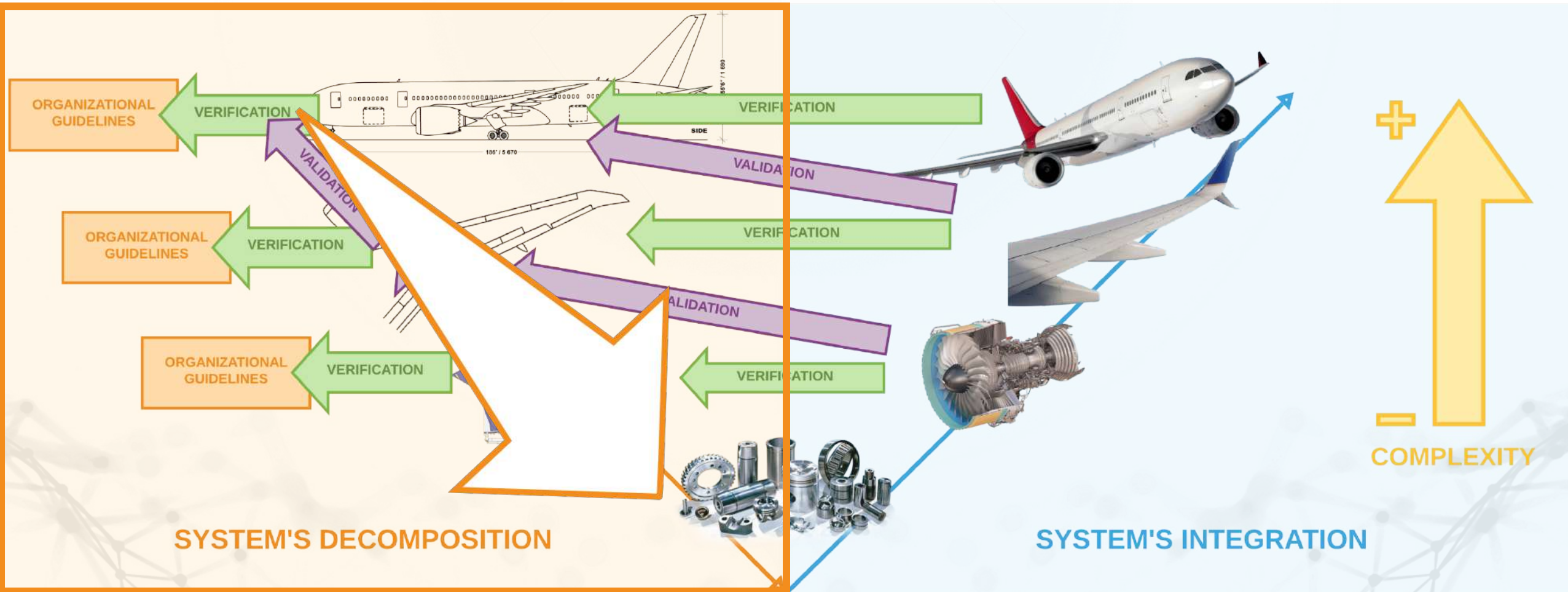


FIGURE 4.17 IPO diagram for the validation process. INCOSE SEH original figure created by Shortell and Walden. Usage per the INCOSE Notices page. All other rights reserved.

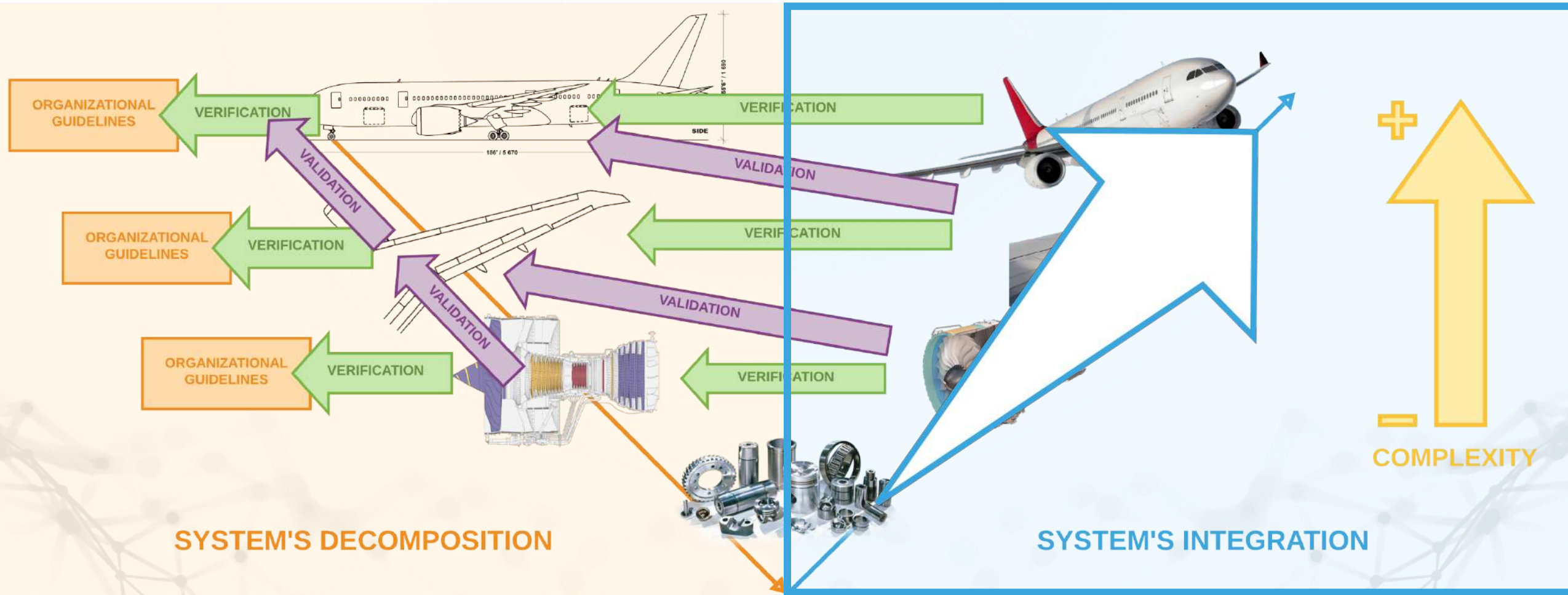
THE V-MODEL



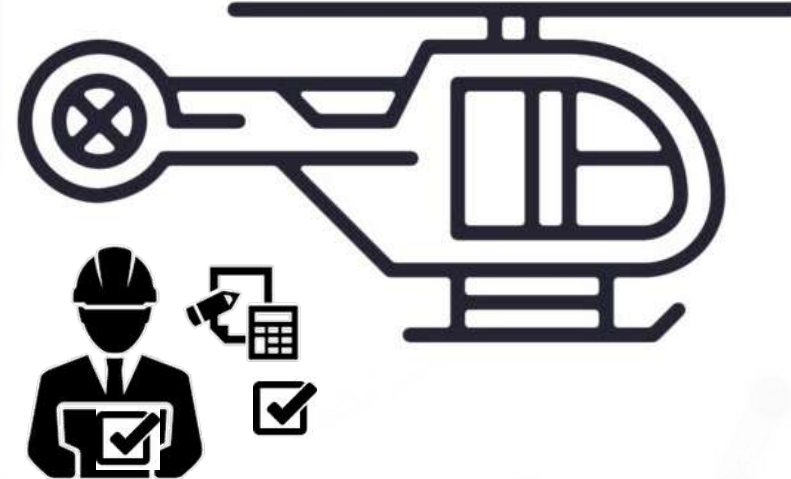
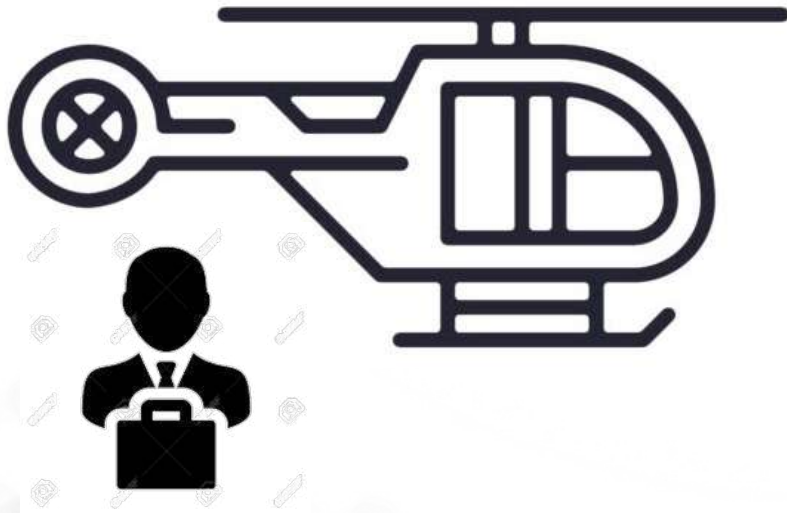
SYSTEM DECOMPOSITION



SYSTEM INTEGRATION



VERIFICATION VS VALIDATION



VERIFICATION VS VALIDATION

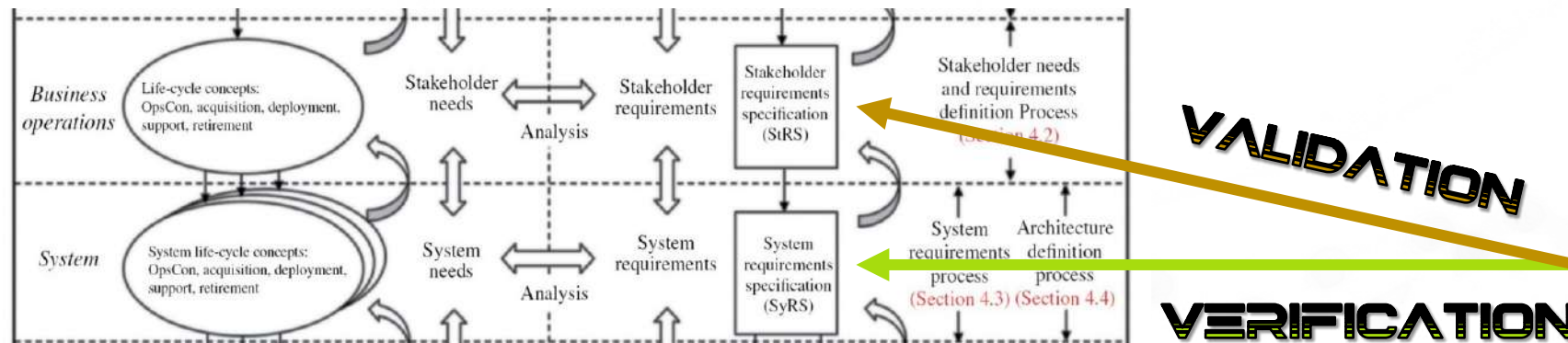
- “The purpose of the **Verification Process** is to provide **OBJECTIVE EVIDENCE** that a system or system element **FULFILLS** its **SPECIFIED REQUIREMENTS AND CHARACTERISTICS.**” (SEHb p.83)
- The purpose of the verification process is to provide EVIDENCE that NO ERROR/DEFECT/FAULT has been introduced at the time of any transformation of inputs into outputs; it is used to confirm that this TRANSFORMATION has been made according to the requirements and selected methods, techniques, standards, or rules.

VERIFICATION VS VALIDATION

- *“The purpose of the **Verification Process** is to provide **OBJECTIVE EVIDENCE** that a system or system element **FULFILLS** its **SPECIFIED REQUIREMENTS AND CHARACTERISTICS**.” (SEHb p.83)*
- The purpose of the verification process is to provide EVIDENCE that NO ERROR/DEFECT/FAULT has been introduced at the time of any transformation of inputs into outputs; it is used to confirm that this TRANSFORMATION has been made according to the requirements and selected methods, techniques, standards, or rules.
- *“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”. (SEHb p.89)*

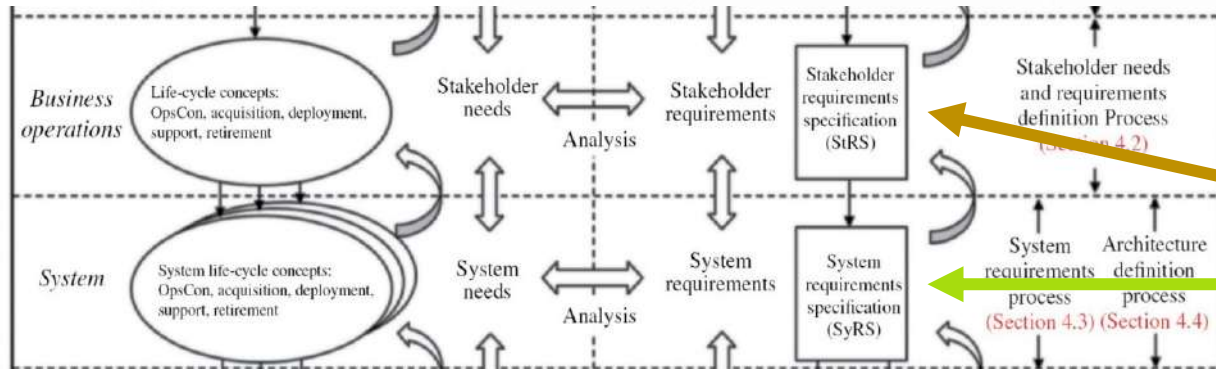
VERIFICATION VS VALIDATION

- “The purpose of the **Verification Process** is to provide **OBJECTIVE EVIDENCE** that a system or system element **FULFILLS** its **SPECIFIED REQUIREMENTS AND CHARACTERISTICS**.” (SEHb p.83)
- The purpose of the verification process is to provide EVIDENCE that NO ERROR/DEFECT/FAULT has been introduced at the time of any transformation of inputs into outputs; it is used to confirm that this TRANSFORMATION has been made according to the requirements and selected methods, techniques, standards, or rules.
- “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”. (SEHb p.89)



Source: Mike Ryan - SE Handbook V4

VERIFICATION VS VALIDATION



Source: Mike Ryan - SE Handbook V4

VALIDATION
VERIFICATION



VALIDATION

“Build the RIGHT THING”

VERIFICATION

“Build the THING RIGHT”

Different CONTEXT

Divergent SCOPE

...

But SAME METHODS and TOOLS

V&V CORE ACTIVITIES

V&V Preparation



- ☞ **Selecting Items** to Verify/Validate.
- ☞ Define a **V&V Action Template**.
- ☞ Specify **Resources, Constraints, Enabling Systems,** etc.
- ☞ Define a **V&V Technique**.

V&V Execution



- ☞ **Execute** the **V&V Action** for each Verifiable Item.
- ☞ Software applies the **OK / KO** decision process based on the **standard guidelines**.
- ☞ **Engineer** defines the **final state** of the Verification process.

V&V Results Management



- ☞ **Manage and record** discovered **anomalies** and **evidences**.
- ☞ Track the **Verification Process** and **manage Configuration**.
- ☞ Build and maintain the **RTVM**.
- ☞ Provide **proper reports**.



CHAPTER 01

PREPARE

V&V PREPARATION



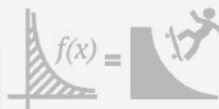
Access the Items to be Verified



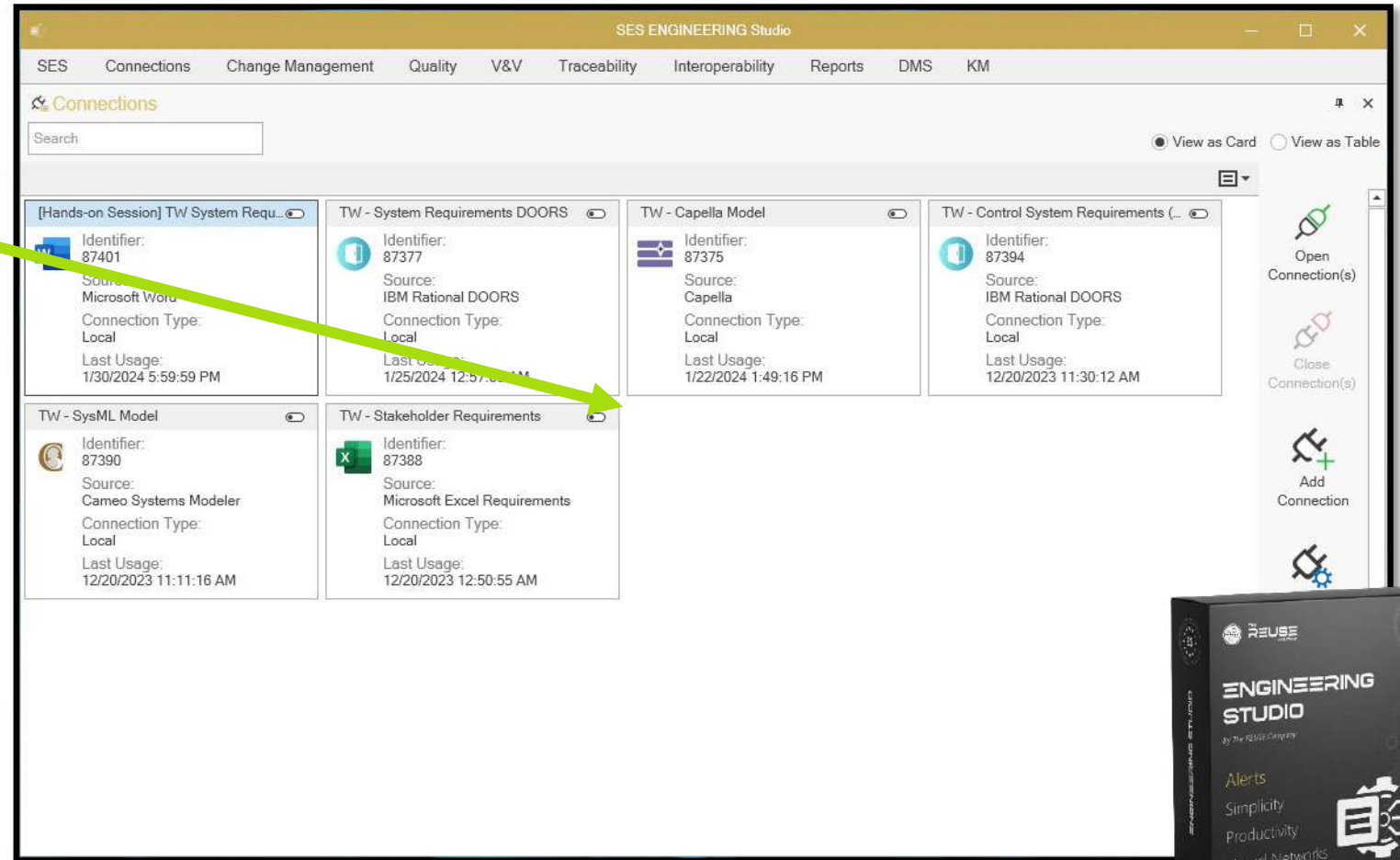
Define a Verification Action for each Verifiable Item



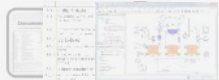
Prepare Resources of all types, Identify constraints, Enabling Systems, etc.



Define a Verification Technique for each Verifiable Item



V&V PREPARATION



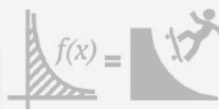
Access the Items to be Verified



Define a Verification Action for each Verifiable Item



Prepare Resources of all types, Identify constraints, Enabling Systems, etc.



Define a Verification Technique for each Verifiable Item

Validation Action

Validatable item:
Description:
The Temperature Warrior shall maintain the environment temperature within the defined range.

Phase:
Navigation:
Details...

Actions:
Validation action from 'Validation'

Validation:
Name:
Validation action from 'Validation action template for specification from 'System Requirements Validation vs Stakeholder Agreements & Regulations''
Technique:
Inspection
Method:
Manual Comparison Rule Checklist Custom action

General Allocation and Properties Deviations & Waivers Remarks & Reserves Document Reference GSN Diagram Interoperability Executions History

General:
Source Items:
Code Name
Objective:
The purpose of this Validation process will be providing objective evidence that the requirements fulfill its intended business and mission objectives according to the NASA standards.
Activity to perform:
1. Open the Validation Checklist.
2. Revise completely the set of questions.
3. Organize the workload according to the Validation topics, teams or experts available.
4. Repeat the following process until every question has been filled-in.
Evaluation:
Expected Evidence:
For this fundamental Validation process, the evidence expected for success will be having at least 75% successful or Not Applicable answers in the Validation Checklist.
Obtained Evidence:
Result:
Validation:
Suggested as not validated
Date:
Agent:
KCS\jose.pereira

Overall result:
Suggested as not validated

Save Current Action



VERIFICATION ACTIONS INSIDE SES ENGINEERING STUDIO

- Record of fields **DIGITALLY** managed and stored in a **DATABASE**.
- Assigned to **EVERY VERIFIABLE ITEM**.
- **RESPONSIBLE ENGINEER** fills it with relevant information.
- **STORE** information for the Verifiable Item to be considered verified.
- **N:N RELATIONSHIP** between *Validatable Items* and *Validation Actions*.

The screenshot displays the 'Validation Action' dialog box in the SES Engineering Studio. The dialog is divided into several sections:

- Validatable item:** Description: "While the Temperature Warrior is in Combat Mode, the Temperature Warrior shall measure the physical environment temperature."
- Actions:** A list of three actions, all derived from a 'Validation action template for specification from System Requirements Validation vs Stakeholder Agreements & Regulations'.
- Validation:** Name: "Validation action from 'Validation action template for specification from System Requirements Validation vs Stakeholder Agreements & Regulations'". Technique: "Inspection". Method: "Manual".
- General:** Source Items: A table with columns 'Code' and 'Name'. Objective: "The purpose of this Validation process will be providing objective evidence that the requirements fulfill its intended business and mission objectives according to the NASA standards." Activity to perform: A list of four steps: 1. Open the Validation Checklist, 2. Revise completely the set of questions, 3. Organize the workload according to the Validation topics, teams or experts available, 4. Repeat the following process until every question has been filled-in.
- Evaluation:** Expected Evidence: "For this fundamental Validation process, the evidence expected for success will be having at least 75% successful or Not Applicable answers in the Validation Checklist." Obtained Evidence: "The validation of SysR-001 has been completed according to the set of validation questions for System Requirements agreed upon. The coverage of positive (or non-applicable) answers is approximately 90%."
- Result:** Validation: "Validated". Date: "2/2/2024 5:23:30 PM". Agent: "KCSyose.pereira". Argumentation: "The Validation Result has been manually set due to fulfilling the condition for validation of having at least 75% of the checklist questions answered successfully (if applicable)." A signature is present.

At the bottom, there is an 'Overall result' section showing 'Suggested as not validated' and a 'Save Current Action' button.

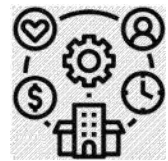
V&V PREPARATION



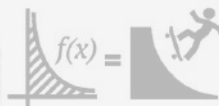
Access the Items to be Verified



Define a Verification Action for each Verifiable Item



Prepare Resources of all types, Identify constraints, Enabling Systems, etc.



Define a Verification Technique for each Verifiable Item

Allocation:		Estimated Labor (Person/Days):	Labor (Person/Days):
Performed by:	Jose Pereira	1	0
Starting Date:	2/1/2024	Ending Date:	
Facility Resources:		Estimated Funds (Currency: €/\$):	Funds (Currency: €/\$):
		250	0
		Estimated Time (Days):	Time (Days):
		1	0



V&V PREPARATION



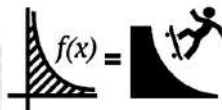
Access the Items to be Verified



Define a Verification Action for each Verifiable Item



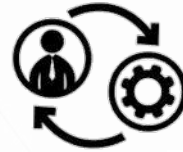
Prepare Resources of all types, Identify constraints, Enabling Systems, etc.



Define a Verification Technique for each Verifiable Item



Select one **Verification Technique** or define your own one.



Define if the obtained results will be gathered manually or automatically.



- **Manually:** (A human engineer fills data in the VA by hand).



Defining customizable Check-lists.



Defining values to be expected.



- **Automatically:** A **Calculation Function** generates the resulting data.



Connecting to other tools.



Calculating the Quality of Verifiable Item using RQA Tool.



Defining your own Calculation Function.





CHAPTER 02

EXECUTE

V&V ACTIVITIES EXECUTION



Execute the Verification Action for each Verifiable Item.



Computer applies the OK / KO decision process based on the standard guidelines.



Engineer defines the final state of the Verification process



SES ENGINEERING Studio

SES Connections Change Management Quality V&V Traceability Interoperability Reports DMS KM

TW - Product Breakdown Structure

Views V&V Shared Save Refresh Close connection

V&V Assurance Project Configuration

Worksheet Selector Current State Snapshot Evolution Scoreboard Dashboard Browser Verifiable Items Matrix Verification View Document Refs Fill V.A. GSN Diagram

PBS Verification Scoreboard Verifiable Items Documentation Options

Drag a column header here to group by that column

	Date Source	Project	Worksheet	ID	Verifiable Item	Verific.	Ver. Status	Verified	Passed	Failed	Others	N. actio...
<input checked="" type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	TW	Temperature Warning			Not treated				
<input type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	CSys	Control System			Not treated				
<input type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	MSys	Management System			Not treated				
<input type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	TASys	Temperature Actuation System			Not treated				
<input type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	TRSys	Temperature Registration System			Not treated				
<input type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	HSysC	Heating System			Not treated				
<input type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	CSysC	Cooling System			Not treated				
<input type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	IVSysC	Information Visualization System			Not treated				
<input type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	TeC	Temperature Controller			Not treated				
<input type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	TiC	Time Controller			Not treated				
<input type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	CFSysC	Configuration System			Not treated				
<input type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	PSys	Power System			Not treated				
<input type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	PSo	Power Source			Not treated				
<input type="checkbox"/>	D:\SE Projects\Temperatu...	TW - Product Breakdown...	PBS	Se	Sensor			Not treated				

Total verifiable items: 14

Hide non-requirement.

Verification Report Verification Forms Verification Author Workprod

Connect to the **Source**
to collect the *Validatable Items*



HOW TO VERIFY & VALIDATE?

1. AUTOMATIC ASSESSMENT:

A human fills information and a computer evaluates a comparison operation.

- ✓ Numeric Comparison: Expected Result vs Obtained Result.
- ✓ Check List results evaluation: (e.g., All values YES → VA OK).
- ✓ Based on the comparison result, the VA gets automatically a *State*.

Evaluation:

Expected Evidence: The registered temperature during the operation scenario 70.2 shall be lower or equal to the defined threshold.

Obtained Evidence:

Expected Numeric Result: 450 Comparison Rule: >= Obtained Numeric Result: 432.8 Tolerance (+/-): 0.5

Checklist:

Answer distribution:

M	Question	Answer	Comment	User
<input type="radio"/>	Are the requirements technically feasible?	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Are all described functions necessary, and together sufficient to meet m...	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Are all required performance specifications and margins listed (eg, con...	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Is each performance requirement realistic?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Are the tolerances overly tight? Are the tolerances defensible and cost...	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Are all external interfaces clearly defined?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Are all internal interfaces clearly defined?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Are all interfaces necessary, sufficient, and consistent with each other?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Have the requirements for maintainability of the system been specified...	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Are requirements written so that ripple effects from changes are minimi...	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Are clearly defined, measurable, and verifiable reliability requirements s...	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Are there error detection, reporting, handling, and recovery requiremen...	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Are undesired events (e.g., single-event upset, data loss or scrambling...	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Have assumptions about the intended sequence of functions been stat...	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Do these requirements adequately address the survivability after a soft...	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Can the system be tested, demonstrated, inspected, or analyzed to sho...	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose
<input type="radio"/>	Are the requirements stated precisely to facilitate specification of syste...	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="radio"/> Not Applicable <input type="radio"/> Empty		KCS\jose

2. MANUAL EVALUATION: A human decides if OK or KO.

Result:

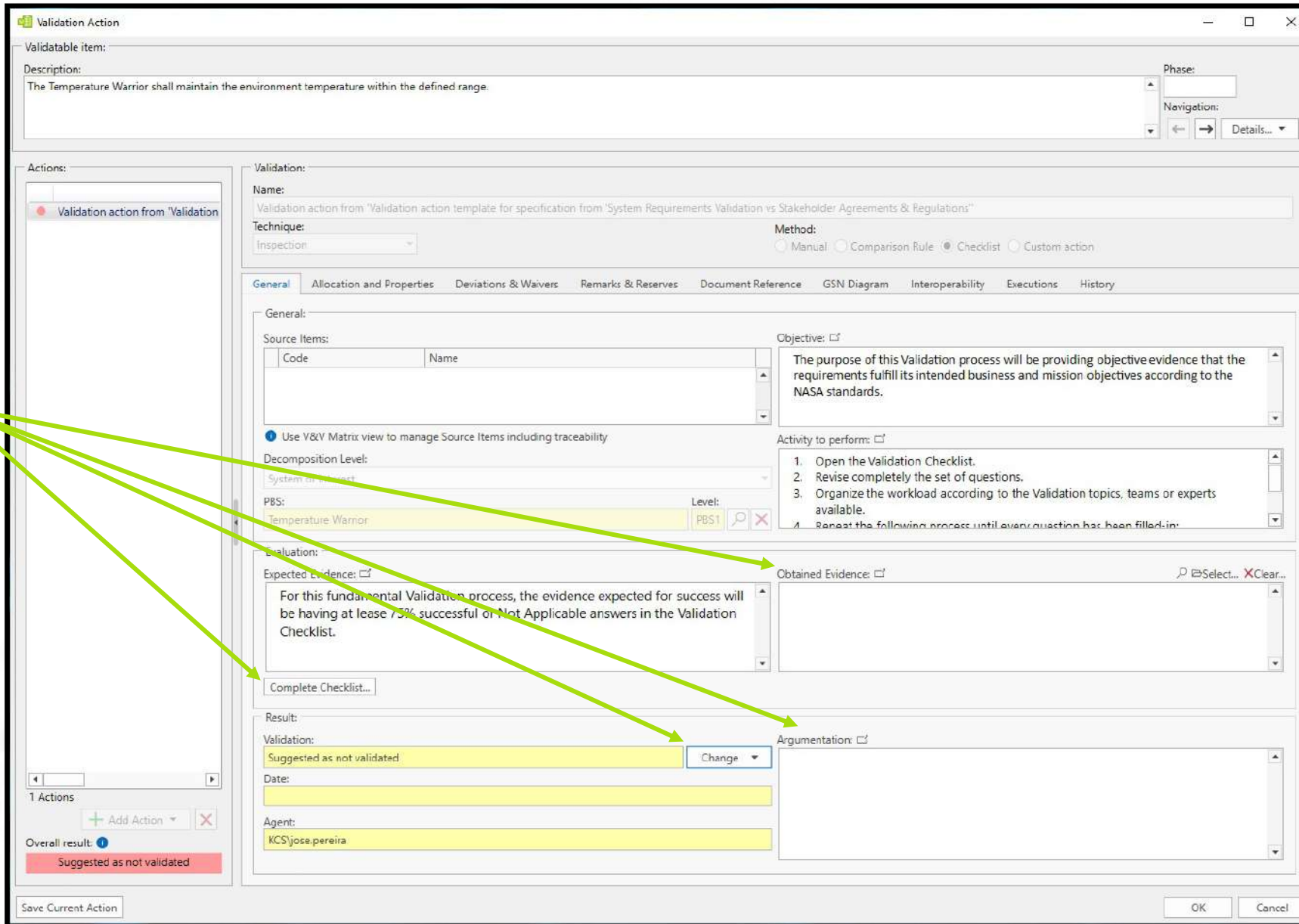
Validation: Validation on going

Date: 2/1/2024 4:45:13 PM

Agent: KCS\jose.pereira

1 Actions

Overall result:



Filled in by **Validation Agents**



V&V Assurance Project Configuration

Module - TW - System Requirements.docx Validation Scoreboard

Data Source	Project	Module	ID	Validatable Item	Validation Phase	Val. Status	Validated	Passed	Failed	Others	N. acti.
N/A	TW - System Requirement	Module - TW - System...	SysR-001	While the Temperature Warrior is in Combat Mode, the Temperature Warrior shall measure the physical environ...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-002	While the Temperature Warrior is in Com...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-003	While the Temperature Warrior is in Com...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-004	While the Temperature Warrior is in Com...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-005	While the Temperature Warrior is in Com...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-006	While the Temperature Warrior is in Com...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-007	While the Temperature Warrior is in Com...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-008	While the Temperature Warrior is in Com...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-009	At the end of each round, the Temperatu...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-010	The Temperature Warrior shall have a Co...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-011	The Temperature Warrior shall have a M...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-012	The Temperature Warrior shall have a Te...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-013	The SIMLAB shall be compatible with an...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-014	The Temperature Warrior shall have a Po...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-015	The Temperature Warrior shall have a Au...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-016	The Temperature Warrior shall have a Co...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-017	The Temperature Warrior shall have a V...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-018	The Temperature Warrior shall have a Re...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-019	The Temperature Warrior shall have a Co...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-020	When the registered temperature exceeds the maximum threshold allowed and the corresponding message has bee...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-021	When the registered temperature exceeds the minimum threshold allowed and the corresponding message has bee...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-022	When the Validation Mode is initialized, the Temperature Warrior shall validate the required parameters, accordi...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-023	When entering Ready Mode, the Temperature Warrior shall display the Ready Mode interface.		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-024	While the Temperature Warrior is in Combat Mode, the Temperature Warrior shall maintain the physical environm...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-025	While the Temperature Warrior is in Combat Mode, the operational activity of the Temperature Warrior shall be auto...		Not treated					
N/A	TW - System Requirement	Module - TW - System...	SysR-026	While the Temperature Warrior is in Configuration Mode, the Temperature Warrior shall allow the configuration of th...		Not treated					

Total validatable items: 147

Validation Report Validation Forms Validation Author Workproduct

Request the tool to
EXECUTE the V&V assessments

N/A	TW - System Requirement	Module - TW - System...	SysR-011	The Temperature Warrior shall have a Management System	01
N/A	TW - System Requirement	Module - TW - System...	SysR-012	The Temperature Warrior shall have a Temperature Actuation System	01
N/A	TW - System Requirement	Module - TW - System...	SysR-013	The Temperature Warrior shall be compatible with an engine allowing to defend from an attack.	02
N/A	TW - System Requirement	Module - TW - System...	SysR-014	The Temperature Warrior shall have a Power System	02
N/A	TW - System Requirement	Module - TW - System...	SysR-015	The Temperature Warrior shall have a Authentication Mode.	02
N/A	TW - System Requirement	Module - TW - System...	SysR-016	The Temperature Warrior shall have a Configuration Mode.	02
N/A	TW - System Requirement	Module - TW - System...	SysR-017	The Temperature Warrior shall have a Validation Mode.	02
N/A	TW - System Requirement	Module - TW - System...	SysR-018	The Temperature Warrior shall have a Ready Mode.	02
N/A	TW - System Requirement	Module - TW - System...	SysR-019	The Temperature Warrior shall have a Combat Mode.	02
N/A	TW - System Requirement	Module - TW - System...	SysR-020	When the registered temperature exceeds the maximum threshold allowed and the corresponding message has bee...	02
N/A	TW - System Requirement	Module - TW - System...	SysR-021	When the registered temperature exceeds the minimum threshold allowed and the corresponding message has bee...	02
N/A	TW - System Requirement	Module - TW - System...	SysR-022	When the Validation Mode is initialized, the Temperature Warrior shall validate the required parameters, accordi...	02
N/A	TW - System Requirement	Module - TW - System...	SysR-023	When entering Ready Mode, the Temperature Warrior shall display the Ready Mode interface.	02
N/A	TW - System Requirement	Module - TW - System...	SysR-024	While the Temperature Warrior is in Combat Mode, the Temperature Warrior shall maintain the physical environm...	02
N/A	TW - System Requirement	Module - TW - System...	SysR-025	While the Temperature Warrior is in Combat Mode, the operational activity of the Temperature Warrior shall be auto...	02
N/A	TW - System Requirement	Module - TW - System...	SysR-026	While the Temperature Warrior is in Configuration Mode, the Temperature Warrior shall allow the configuration of th...	02

Total validatable items: 147

Validation Report Validation Forms Validation Author Workproduct

Validation Scoreboard

Val. Status	Validated	Passed	Failed	Others	N. acti.
Suggested as not validated	1	1	1	1	3
Not validated	0	1	0	1	
Not validated	0	1	0	1	
Validated	1	0	0	1	
Validated	1	0	0	1	
Not validated	0	1	0	1	
Not validated	0	1	0	1	
Not validated	0	1	0	1	
Validated	0	0	1	1	
Validated	0	0	1	1	
Validated	1	0	0	1	
Not validated	0	1	0	1	
Validated	1	0	0	1	
Not validated	0	1	0	1	
Validated	1	0	0	1	

Validation Report Validation Forms Validation Author Workproduct



V&V ACTIVITIES EXECUTION



Execute the Verification Action for each Verifiable Item.

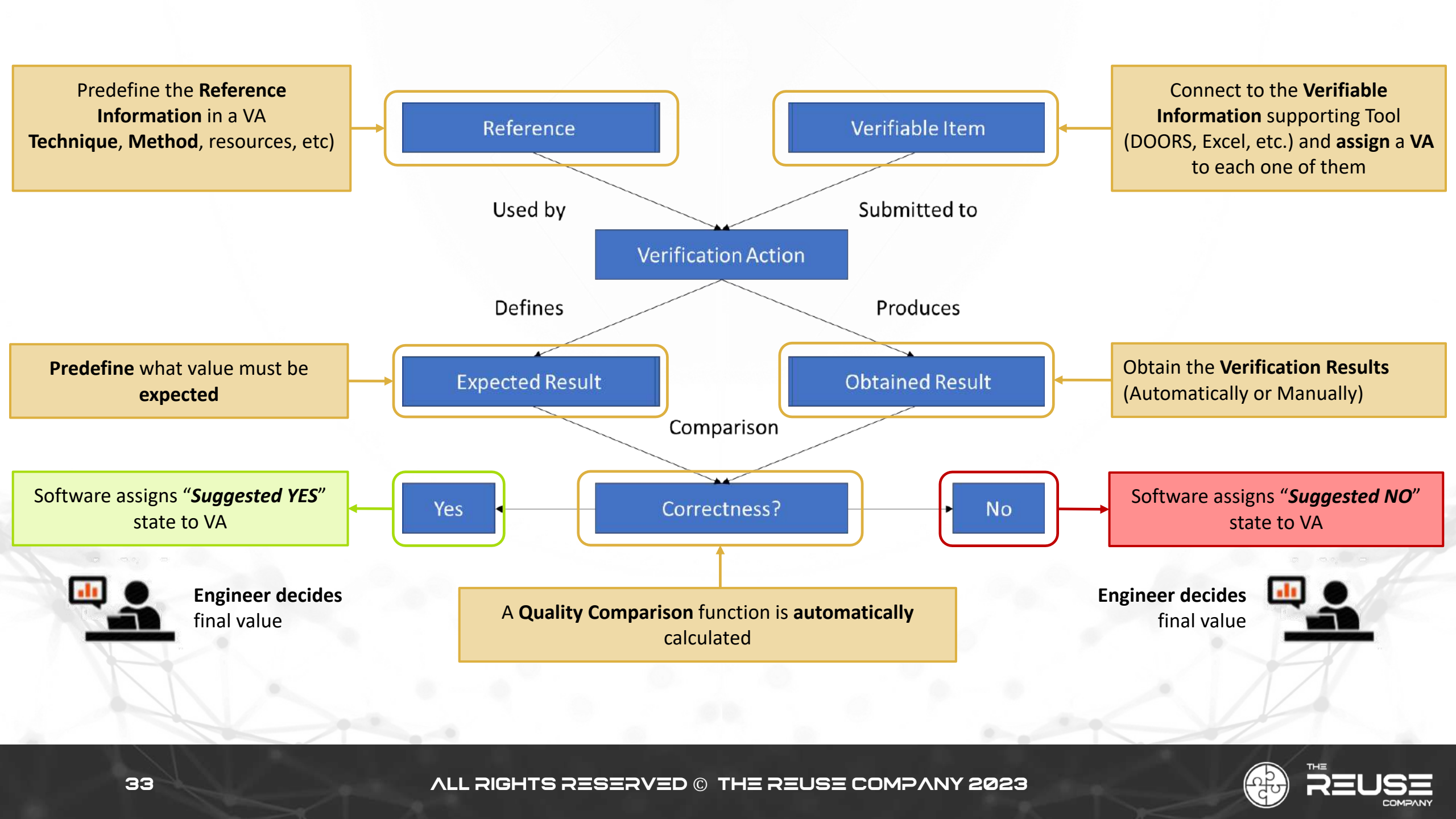


Computer applies the OK / KO decision process based on the standard guidelines.



Engineer defines the final state of the Verification process





V&V ACTIVITIES EXECUTION



Execute the Verification Action for each Verifiable Item.



Computer applies the OK / KO decision process based on the standard guidelines.



Engineer defines the final state of the Verification process



The **engineer** provides the **final state** for the **V&V Action** (and cannot be altered by the tool).

The screenshot shows the 'Validation Action' window in V&V Studio. The 'Validation' section is highlighted in yellow, and a 'Change' dropdown menu is open, showing options like 'Validated', 'Not validated', and 'Validation on going'. A green arrow points from the text on the left to the 'Validation on going' status in the dropdown menu.

Validation Action

Validatable item:

Description: The Temperature Warrior shall maintain the environment temperature within the defined range.

Phase: []

Navigation: [] [] [] Details...

Actions:

- Validation action from 'Validation action t

Validation:

Name: Validation action from 'Validation-action template for specification from 'System Requirements Validation vs Stakeholder Agreements & Regulations''

Technique: Inspection

Method: Manual Comparison Rule Checklist Custom action

General Allocation and Properties Deviations & Waivers Remarks & Reserves Document Reference GSN Diagram Interoperability Executions History

System of interest: []

PBS: Temperature Warrior Level: PBS1

2. Revise completely the set of questions.
3. Organize the workload according to the Validation topics, teams or experts available.
4. Repeat the following process until every question has been filled-in:

Evaluation:

Expected Evidence: []

Obtained Evidence: [] [Select...] [Clear...]

For this fundamental Validation process, the evidence expected for success will be having at least 75% successful or Not Applicable answers in the []

Complete Checklist

Result:

Validation: Validation on going [Change]

Date: 2/1/2024 5:02:38 PM

Agent: KCS\jose.pereira

Argumentation: []

The validation process is still pending to be completed. Remaining 14, and 56 from the validation checklist to reach the minimum

1 Actions

Overall result: 1

Validation on going

Save Current Action

Change dropdown menu options:

- Validation not applicable
- Suggested as validated
- Suggested as not validated
- Validated
- Not validated
- Validation on going



Validation Action

Validatable item:

Description:
The Temperature Warrior shall maintain the environment temperature within the defined range.

Phase: []
Navigation: [] [] [] [Details...]

Actions:

- Validation action from "Validation action t

Validation:

Name:
Validation action from "Validation action template for specification from "System Requirements Validation vs Stakeholder Agreements & Regulations"

Technique: [Inspection] Method: Manual Comparison Rule Checklist Custom action

General | Allocation and Properties | Deviations & Waivers | Remarks & Reserves | Document Reference | GSN Diagram | Interoperability | Executions | History

System of interest: []
PBS: [Temperature Warrior] Level: [PBS1] [] []
2. Revise completely the set of questions.
3. Organize the workload according to the Validation topics, teams or experts available.
4. Repeat the following process until every question has been filled in:

Evaluation:

Expected Evidence: []
Obtained Evidence: [] [Select...] [Clear...]
For this fundamental Validation process, the evidence expected for success will be having at least 75% successful or Not Applicable answers in the []
Complete Checklist...

Result:

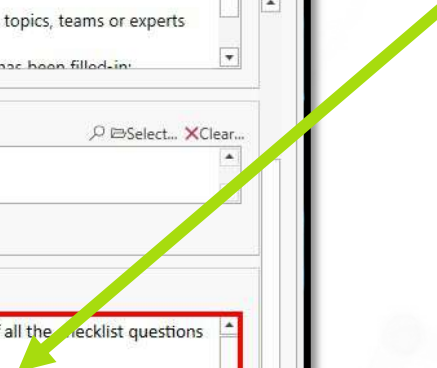
Validation: [Validated] [Change]
Date: [2/1/2024 5:02:38 PM]
Agent: [KCS\jose.pereira]

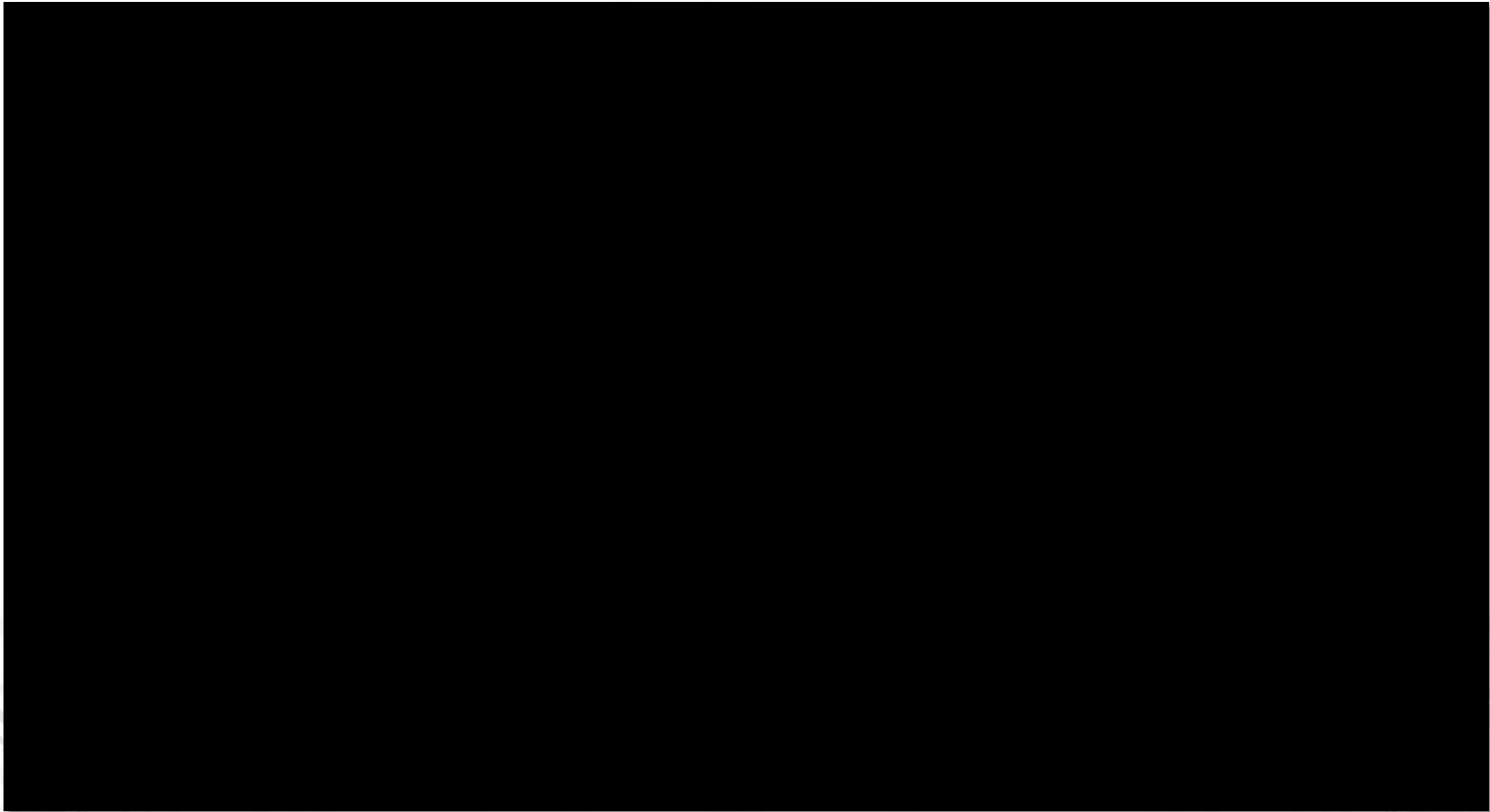
Argumentation: []
The validation process completed, reaching an 80% of all the checklist questions answered positively (if applicable).
P. Pereira

Overall result: [Validated]

Save Current Action [] [OK] [Cancel]

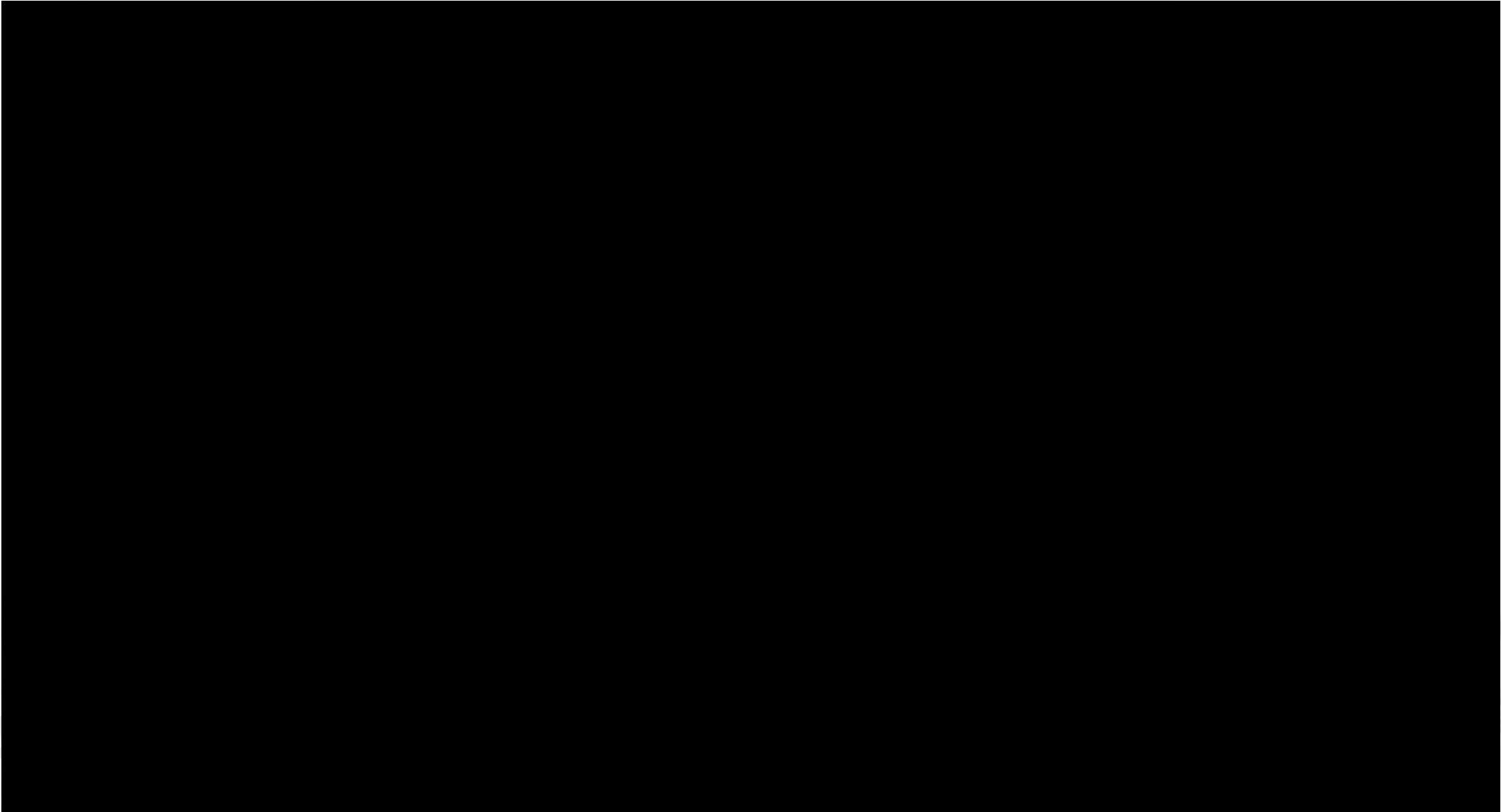
Then provides the argumentation, and the new status is registered.







CHAPTER 03
RESULTS
MANAGEMENT





**COMING UP
WEBINAR!**



COMING UP WEBINAR!

MEETING ISO 13485 REQUIREMENTS ON DESIGN AND DEVELOPMENT INPUTS BY APPLYING AI TECHNOLOGY

27-Feb-2023 – 17:00 CET

29-Feb-2023 – 09:00 CET



PETER SEBELIUS
CEO GANTUS AB



CHRISTER FRÖLING
SALES MANAGER



**QUESTIONS,
COMMENTS!**



THE
REUSE
COMPANY

