

# Meeting ISO 13485 requirements on design and development inputs by applying AI technology



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THE  
**REUSE**  
COMPANY

Introduction to The REUSE Company and Medical Device HQ

01

02

03

04

05

Requirements characteristics according to ISO 13485

Introduction to the SES ENGINEERING Studio (SES)

Q&A

Demo different Use Cases with SES



The REUSE Company is a tool vendor specialized in the application of **semantic technologies** and artificial intelligence to improve the **digitalization of the Engineering** processes.



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Christer Fröling is a Swedish citizen acting in the role of the **CEO for Reuse Company Scandinavia**. He has over **two decade of experience** in successful implementation of **Systems Engineering (SE)** and its sub-disciplines in a variety of roles and technical domains.

He has **experience** from both **developing advanced technical systems** as well as **helping public organizations** in the specification and **procurement** of complex infrastructure projects.

Christer specializes as a **principal consultant in applying SE and “design thinking”** into organizations willing to adopt change and implement a **knowledge driven** and **Lean SE approach** focusing on information quality, knowledge buildup and reuse with a passion of coaching others.

He is an **appreciated lecturer, teacher** and a strong **believer in knowledge sharing** and networking.



Peter Sebelius



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Peter Sebelius is a highly esteemed trainer, consultant, and entrepreneur in the medical device industry. He is a member of the Joint Working Group that authors the ISO 13485 and ISO 14971 standards.

He has vast ‘hands-on’ experience, having developed, amongst other things, a mechanical chest compression device and an ex vivo perfusion machine for the lungs. He has received numerous awards including the Great Design Award and the title “This year’s specialist” by Veckans Affärer.

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Standards / norms

- MDR (14)
- ISO 13485 (12)
- IVDR (7)
- ISO 14971 (7)
- QSR (5)
- IEC 62304 (4)
- IEC 62366-1 (4)
- IEC 82304-1 (4)
- IEC 60601-1 (2)
- ISO 14155 (1)

Course topics

- Design control (5)
- Risk management (5)
- Software development (4)
- Quality management (3)

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ADVANCED RISK MANAGEMENT FOR

**Requirements  
according to ISO 13485  
Characteristics  
and Rules**

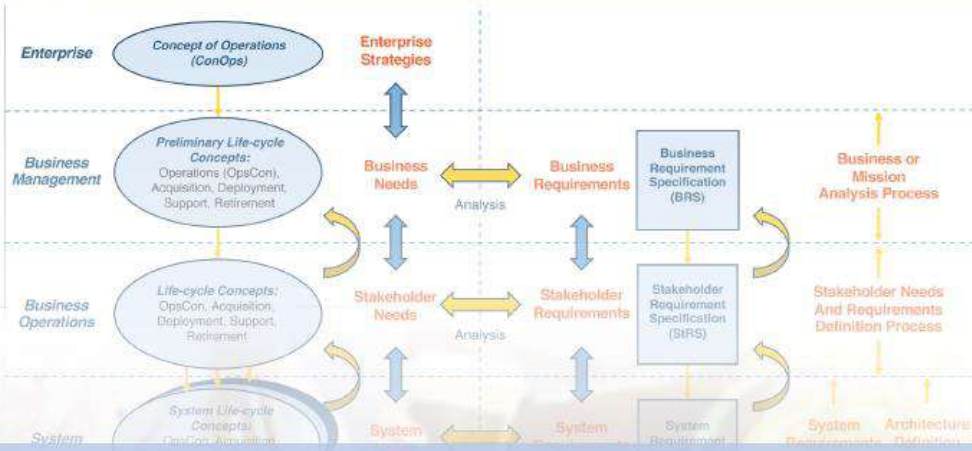
Are requirements important?

# What should design and development inputs be like?

Design and development input characteristics according to ISO 13485:

- Complete
- Unambiguous
- Able to be verified
- Able to be validated
- Not in conflict with each other

# INCOSE



## Guide to Writing Requirements

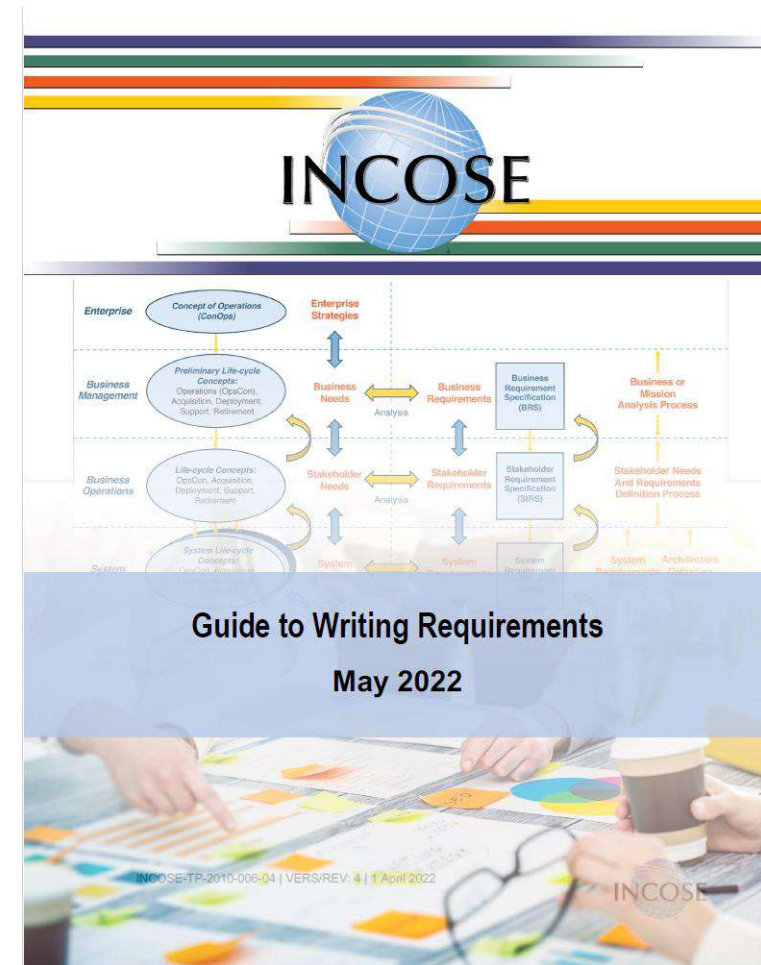
May 2022



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	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R
1			Characteristics for individual needs and requirements									Characteristics for sets of needs and requirements					
2	Rule	Subject	Necessary	Appropriate	Unambiguous	Complete*	Singular	Feasible	Verifiable*	Correct	Conforming	Complete	Consistent	Feasible	Comprehensiv	Able to be validated*	Applicable ISO 13485
3	R1	Structured, complete sentence			X	X			X	X	X						Yes
4	R2	Use active voice		X	X	X			X								Yes
5	R3	Use appropriate subject verb		X	X				X			X				X	Yes
6	R4	Define terms			X				X				X			X	Yes
7	R5	Use definite article "the" vs "a"			X				X								Yes
8	R6	Use appropriate units			X	X			X	X							Yes
9	R7	Avoid vague terms			X	X			X								Yes
10	R8	Avoid escape clauses			X				X								Yes
11	R9	Avoid open-ended clauses			X	X	X		X								Yes
12	R10	Avoid superfluous infinitives			X				X								Yes
13	R11	Use a separate clause			X	X			X	X							Yes
14	R12	Use correct grammar			X				X	X	X						Yes
15	R13	Use correct spelling			X				X								Yes
16	R14	Use correct punctuation			X					X							Yes
17	R15	Logical expressions			X				X								Yes
18	R16	Avoid the use of "not."			X				X	X							Yes
19	R17	Avoid the oblique ("/") symbol			X				X								Yes
20	R18	Use single thought sentence			X		X		X		X				X		Yes
21	R19	Avoid combinators			X		X										Yes
22	R20	Avoid phrases of purpose or reason	X				X										
23	R21	Avoid parentheses & brackets					X										
24	R22	Enumerate sets explicitly			X		X										Yes
25	R23	Supporting diagram or model			X	X	X										Yes
26	R24	Avoid pronouns & indefinite pronouns			X	X			X								Yes
27	R25	Avoid relying on headings				X											Yes
28	R26	Avoid using unachievable absolutes						X	X	X			X				Yes
29	R27	State applicability conditions explicitly				X			X	X							Yes
30	R28	Single condition for a specific action			X				X								Yes
31	R29	Classify by type or category										X	X				
32	R30	Express once and only once	X								X		X				
33	R31	Avoid stating a solution		X													
34	R32	Use "each" for universal quantification			X				X	X							Yes
35	R33	Define quantities with a range of values			X	X		X	X	X			X				Yes
36	R34	Specific measurable performance targets			X	X			X				X				Yes
37	R35	Define temporal dependencies explicitly			X	X			X								Yes
38	R36	Use terms & units of measure consistently			X					X	X		X		X	X	Yes
39	R37	Use a consistent set of acronyms			X						X		X		X	X	Yes
40	R38	Avoid the use of abbreviations									X		X		X	X	Yes
41	R39	Use a project-wide style guide				X	X				X		X		X	X	Yes
42	R40	Group related needs & requirements				X					X	X	X		X		Yes
43	R41	Conform to a defined structure or template										X	X		X	X	Yes

# Example rules (1)

The structure of design input requirements statements must be in the form of a complete sentence, the simplest form of which is:

<subject> <verb> <object>.

Bad example:

Output flow > 100 ml/min

Good example:

The Xmed device shall output water with a flow of >100 ml/min.

# Examples rules (2)

Repeat nouns in full instead of using pronouns to refer to nouns in other need or requirement statements.

Pronouns are words such as “it”, “this”, “that”, “he”, “she”, “they”, and “them.”

Bad example:

When the Xmed device is connected to the ventilator, it shall confirm the connection with audio signal.

Good example:

When the Xmed device is connected to the ventilator, the Xmed device shall confirm the connection with audio signal.

# Examples rules (3)

All numbers should have units of measure explicitly stated in terms of the measurement system used or the thing the number refers.

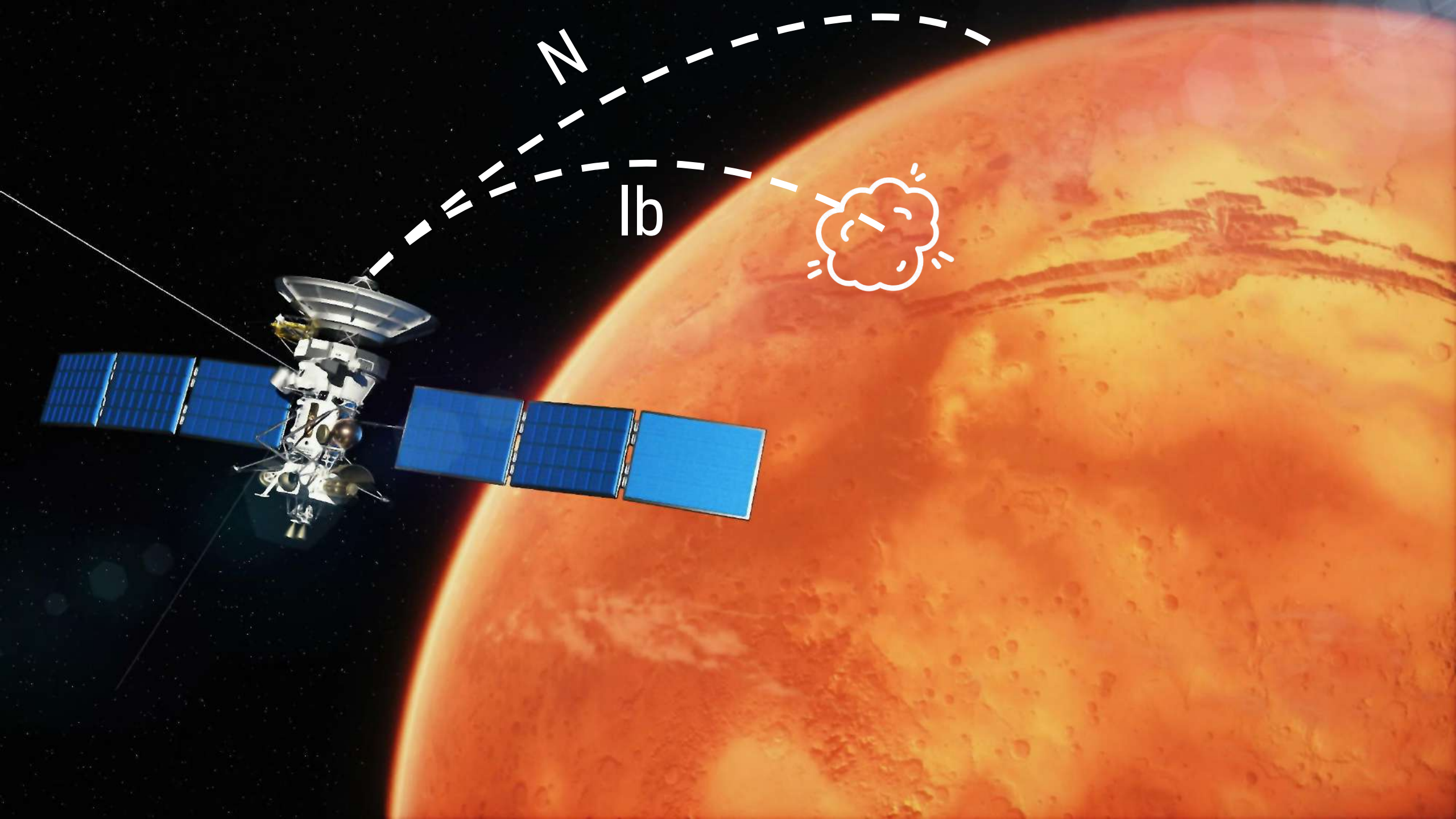
Within a project, a common measurement system must be used consistently. For example, do not mix both US and metric units of measure within any of the project's artifacts.

Bad example:

The Printed Circuit Board temperature shall not exceed 5 degrees.

Good example:

The Printed Circuit Board temperature shall not exceed 5°Celsius.



## User story patterns:

- As a <who>, I want <what> so that <why>.

## User story patterns:

- As a <who>, I want <what> so that <why>.

## Example:

- As a nurse, I want to see the patient's temperature for the preceding 30 minutes so that I know if something happened to the patient.

# Examples of patterns

- User stories
- Need statement pattern (INCOSE)
- Requirement statement patterns (INCOSE)
- Use cases
- Operational scenarios
- Epics, features and stories (Scaled Agile Framework)
- EARS (Easy Approach to Requirements Syntax)

Design input requirement pattern:

- The <entity> shall <entity response>.

Design input requirement pattern:

- The <entity> shall <entity response>.

Example:

- The SoCool device shall weigh less than 8 kg.

# EARS requirement patterns

Requirement / pattern	Description	Pattern	Example
Ubiquitous	Always active. Not called for by an input or event.	The <entity> shall <entity response>.	The SoCool device shall be less than 50 cm wide.
Event-driven	Requires a response when the system detects an external event.	When <trigger> the <system name> shall <system response>.	When the escape button is pressed, the SoCool device shall show the home screen.
State-driven	Active while a defined state is true.	While <in a specific state> the <system name> shall <system response>.	While the safety button is engaged, the biopsy needle gun shall prevent the needle from being fired.
Unwanted behavior	Covers all undesirable situations.	If <trigger>, then the <system name> shall <system response>.	If the SoCool device leaks more than 50 ml of water inside, then the SoCool device shall shut down.

# EARS requirement patterns

Requirement / pattern	Description	Pattern	Example
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State-driven	Active while a defined state is true.	While <in a specific state> the <system name> shall <system response>.	While the safety button is engaged, the biopsy needle gun shall prevent the needle from being fired.
Unwanted behavior	Covers all undesirable situations.	If <trigger>, then the <system name> shall <system response>.	If the SoCool device leaks more than 50 ml of water inside, then the SoCool device shall shut down.



## The bad example

The Xmed device shall have as low weight as possible.



## The good example

The Xmed device shall weigh less than TBD kg.

### Problem:

- Uses an escape clause

## INTRODUCTION TO MEDICAL DEVICE REQUIREMENTS ENGINEERING

### ONLINE COURSE

Learn about writing medical device user needs and design input requirements in this self-paced, interactive online course.

We recommend that you take the [design control course](#) before this course unless you already have a good understanding of design control.



### ONLINE COURSE

Course length

10-15 hours

Course fee  
(per person)

from € 299

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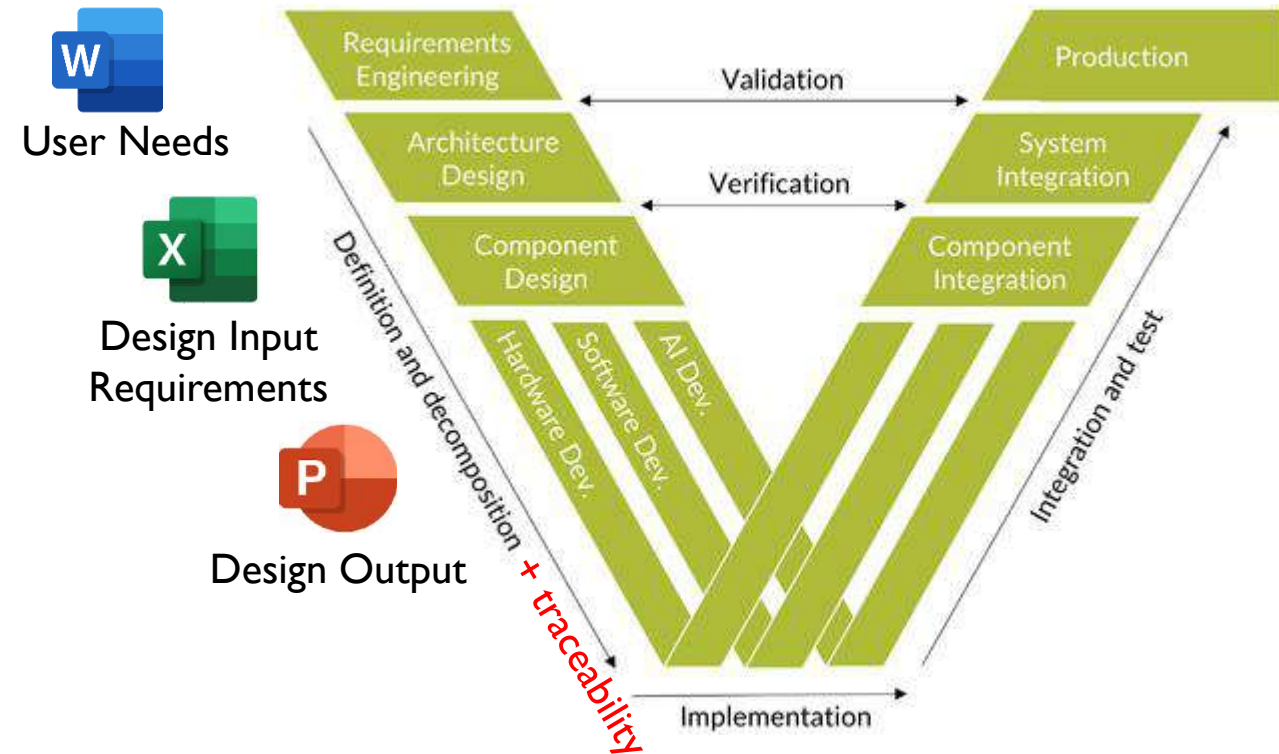


# Introduction to Systems Engineering Suite (SES)



## The background that developed SES Engineering studio

- ▶ Organisations are still immature in Requirements- and Systems Engineering
- ▶ Dispersed and stove piped development
- ▶ Little focus on Knowledge Management or work product quality
- ▶ Multiple tools involved and now clear workflows defined according to the ISO 15288 technical processes
- ▶ No tools interoperability
- ▶ No Reuse of information between projects

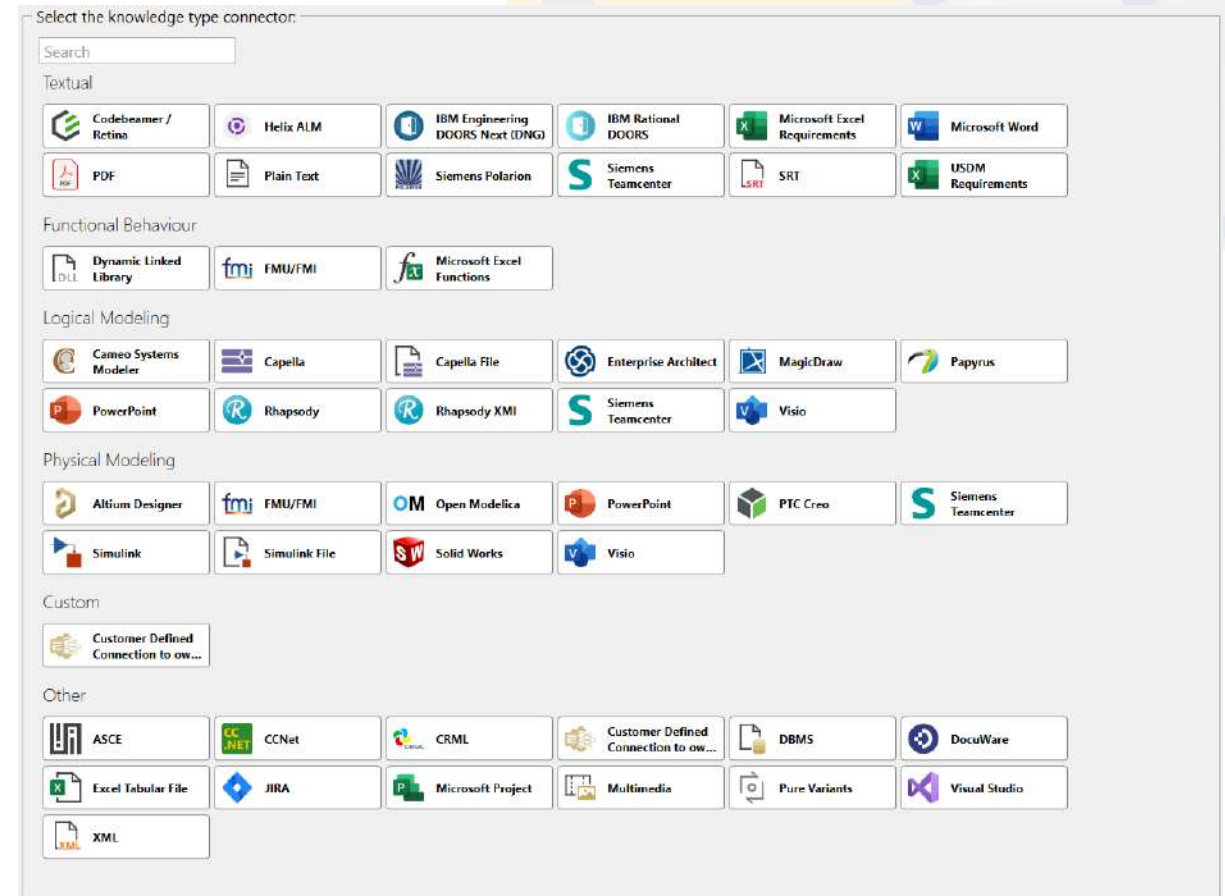




- RQA – QUALITY Studio
- RAT – AUTHORIZING Tool
- KM – Knowledge Manager
- TRACEABILITY Studio
- V&V Studio
- REx – REQUIREMENTS Engineering Tool for MS Word
- SES ENGINEERING Studio

## Connectivity and Interoperability

- ▶ Ensuring a digital seamless workflow
- ▶ Technical project management and KPI's
- ▶ Traceability in all connectors
- ▶ Configuration and Change Management
- ▶ Knowledge Management
- ▶ ..Future capabilities;
  - ▶ Decision Management (AI)
  - ▶ Risk Management
  - ▶ Product line engineering (PLE)
  - ▶ ..etc



## 05 Reasoning

A combination of rules, tasks and groups to infer information from valuable assets

## 04 Formalization

Representation of assets semantic through SRL – System Representation Language



## 01

### Vocabulary

Controlled Organizational and Project Vocabulary for a common understanding among stakeholders

## 02

### SCM/Architectures

Recreate and capture the system architectures represented in views and models. Stablish relationships among system and system elements

## 03

### Patterns

Represent requirements similarities and enable formal representation, automatic recognition and aid authors



## **Live Demo**

SES applied for  
the ISO13485  
scenario

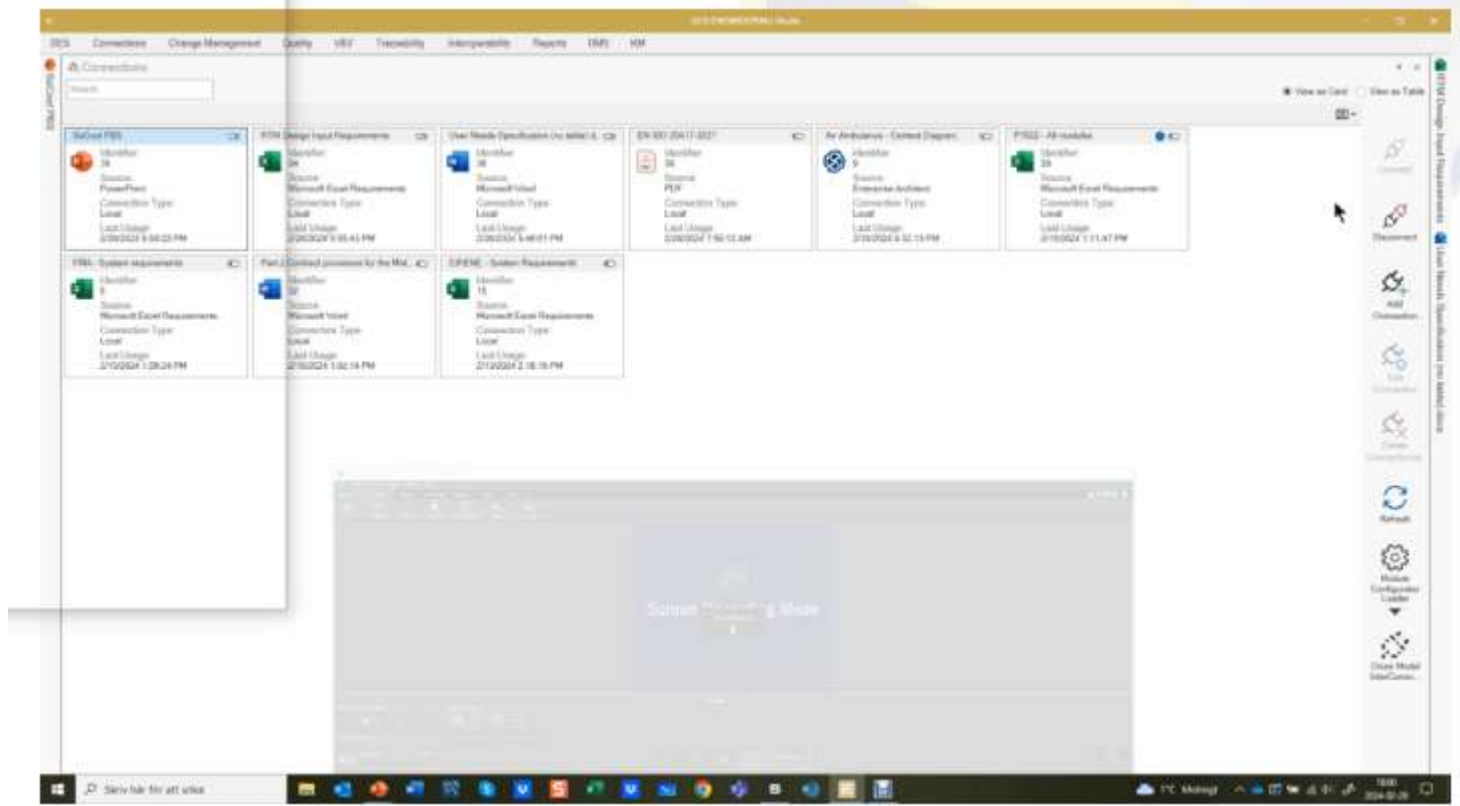
## Use Case #1 – Open different types of connectors and show attributes

### Different connectors

- ▶ Open User Needs in MS Word
- ▶ Open Design Output (PBS) in MS PowerPoint
- ▶ Open Design Input requirements in MS Excel

### Quality Analysis

- ▶ Analysis of the Design Input requirements with a ISO 13485 adopted metric set
- ▶ Show the quality report



# Use Case #2 – Change a requirement and create a new using an EARS pattern

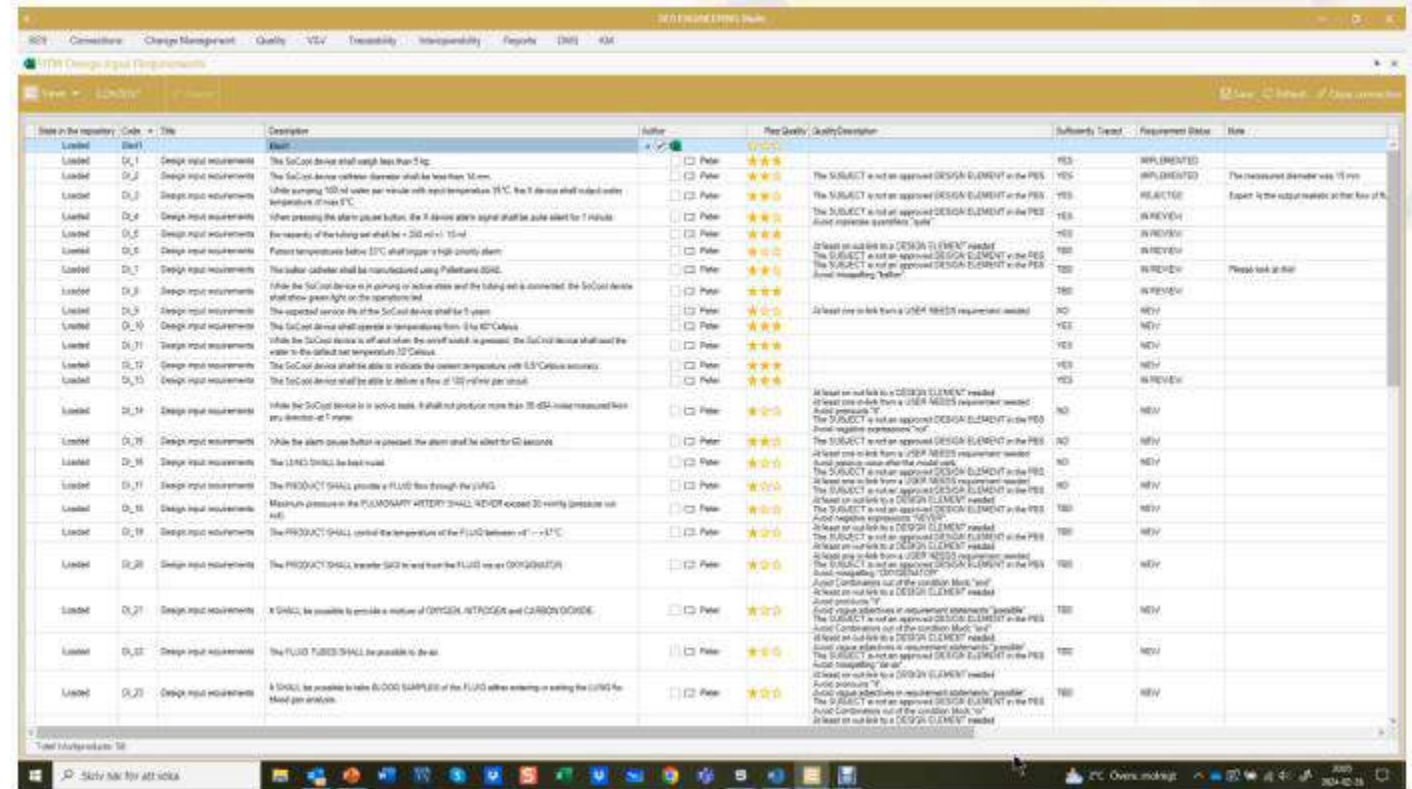
## Change a requirement

- ▶ Open Design Input requirements in MS Excel

- ▶ Change an existing requirement

## Create a new requirement

- ▶ Open the editor (RAT) and create a new requirement with writing assistance



State in the repository	Code	Title	Description	Author	Peer Quality	Quality/Description	Subjunctively Tested	Requirement Status	Note
Loaded	DI_1	Design input requirements	The SoCool device shall weigh less than 5 kg.	Peter	☆☆☆☆		YES	IMPLEMENTED	
Loaded	DI_2	Design input requirements	The SoCool device cabinet diameter shall be less than 10 cm.	Peter	☆☆☆☆		YES	IMPLEMENTED	The measured diameter was 10 mm
Loaded	DI_3	Design input requirements	While running, 100 ml water per minute with input temperature 15°C, the 3 liter device shall maintain water temperature at max 5°C.	Peter	☆☆☆☆	The SUBJECT is not an approved DESIGN ELEMENT in the PES	YES	REJECTED	Expert in the output market at the time of R.
Loaded	DI_4	Design input requirements	When pressing the start button, the 3 liter device shall be able to start for 7 minutes	Peter	☆☆☆☆	The SUBJECT is not an approved DESIGN ELEMENT in the PES	YES	IN REVIEW	
Loaded	DI_5	Design input requirements	For necessity of the tubing set shall be <math>300 \text{ ml} \times 1.5 \text{ m}</math>	Peter	☆☆☆☆	At least one link to a DESIGN ELEMENT needed	YES	IN REVIEW	
Loaded	DI_6	Design input requirements	For necessity of the tubing set shall be <math>300 \text{ ml} \times 1.5 \text{ m}</math>	Peter	☆☆☆☆	The SUBJECT is not an approved DESIGN ELEMENT in the PES	YES	IN REVIEW	
Loaded	DI_7	Design input requirements	For necessity of the tubing set shall be <math>300 \text{ ml} \times 1.5 \text{ m}</math>	Peter	☆☆☆☆	The SUBJECT is not an approved DESIGN ELEMENT in the PES	YES	IN REVIEW	Please link to this
Loaded	DI_8	Design input requirements	The holder cabinet shall be manufactured using Polylactide 3000L	Peter	☆☆☆☆		YES	IN REVIEW	
Loaded	DI_9	Design input requirements	While the SoCool device is in charging or active state and the tubing set is connected, the SoCool device shall show green light on the front panel	Peter	☆☆☆☆		YES	IN REVIEW	
Loaded	DI_10	Design input requirements	The expected service life of the SoCool device shall be 5 years	Peter	☆☆☆☆	At least one link from a USER NEEDS requirement needed	NO	NEW	
Loaded	DI_11	Design input requirements	While the SoCool device is off and when the start button is pressed, the SoCool device shall heat the water in the cabinet to temperature 30 Celsius	Peter	☆☆☆☆		YES	NEW	
Loaded	DI_12	Design input requirements	The SoCool device shall be able to indicate the current temperature with 0.5°C Celsius accuracy	Peter	☆☆☆☆		YES	NEW	
Loaded	DI_13	Design input requirements	The SoCool device shall be able to deliver a flow of 100 ml/min per stroke	Peter	☆☆☆☆		YES	IN REVIEW	
Loaded	DI_14	Design input requirements	While the SoCool device is in active mode, it shall not produce more than 30 dB(A) noise measured from any direction at 1 meter	Peter	☆☆☆☆	At least one link to a DESIGN ELEMENT needed	NO	NEW	
Loaded	DI_15	Design input requirements	While the SoCool device is in active mode, it shall not produce more than 30 dB(A) noise measured from any direction at 1 meter	Peter	☆☆☆☆	The SUBJECT is not an approved DESIGN ELEMENT in the PES	NO	NEW	
Loaded	DI_16	Design input requirements	While the SoCool device is in active mode, it shall not produce more than 30 dB(A) noise measured from any direction at 1 meter	Peter	☆☆☆☆	The SUBJECT is not an approved DESIGN ELEMENT in the PES	NO	NEW	
Loaded	DI_17	Design input requirements	The PROXYACT SHALL provide a FLUID flow through the LUNG	Peter	☆☆☆☆	At least one link from a USER NEEDS requirement needed	NO	NEW	
Loaded	DI_18	Design input requirements	Maximum pressure in the PULMONARY ARTERY SHALL NEVER exceed 30 mmHg (systolic not full)	Peter	☆☆☆☆	At least one link to a DESIGN ELEMENT needed	YES	NEW	
Loaded	DI_19	Design input requirements	The PROXYACT SHALL transfer the temperature of the FLUID between <math>0^{\circ}\text{C}</math> - <math>41^{\circ}\text{C}</math>	Peter	☆☆☆☆	The SUBJECT is not an approved DESIGN ELEMENT in the PES	YES	NEW	
Loaded	DI_20	Design input requirements	The PROXYACT SHALL transfer SO2 from the FLUID to the OXYGENATOR	Peter	☆☆☆☆	The SUBJECT is not an approved DESIGN ELEMENT in the PES	YES	NEW	
Loaded	DI_21	Design input requirements	It SHALL be possible to provide a mixture of OXYGEN, NITROGEN and CARBON DIOXIDE	Peter	☆☆☆☆	At least one link to a DESIGN ELEMENT needed	YES	NEW	
Loaded	DI_22	Design input requirements	The FLUID FLOWS SHALL be possible to be set	Peter	☆☆☆☆	At least one link to a DESIGN ELEMENT needed	YES	NEW	
Loaded	DI_23	Design input requirements	It SHALL be possible to take BLOOD SAMPLES of the FLUID either entering or exiting the LUNG for blood gas analysis	Peter	☆☆☆☆	At least one link to a DESIGN ELEMENT needed	YES	NEW	

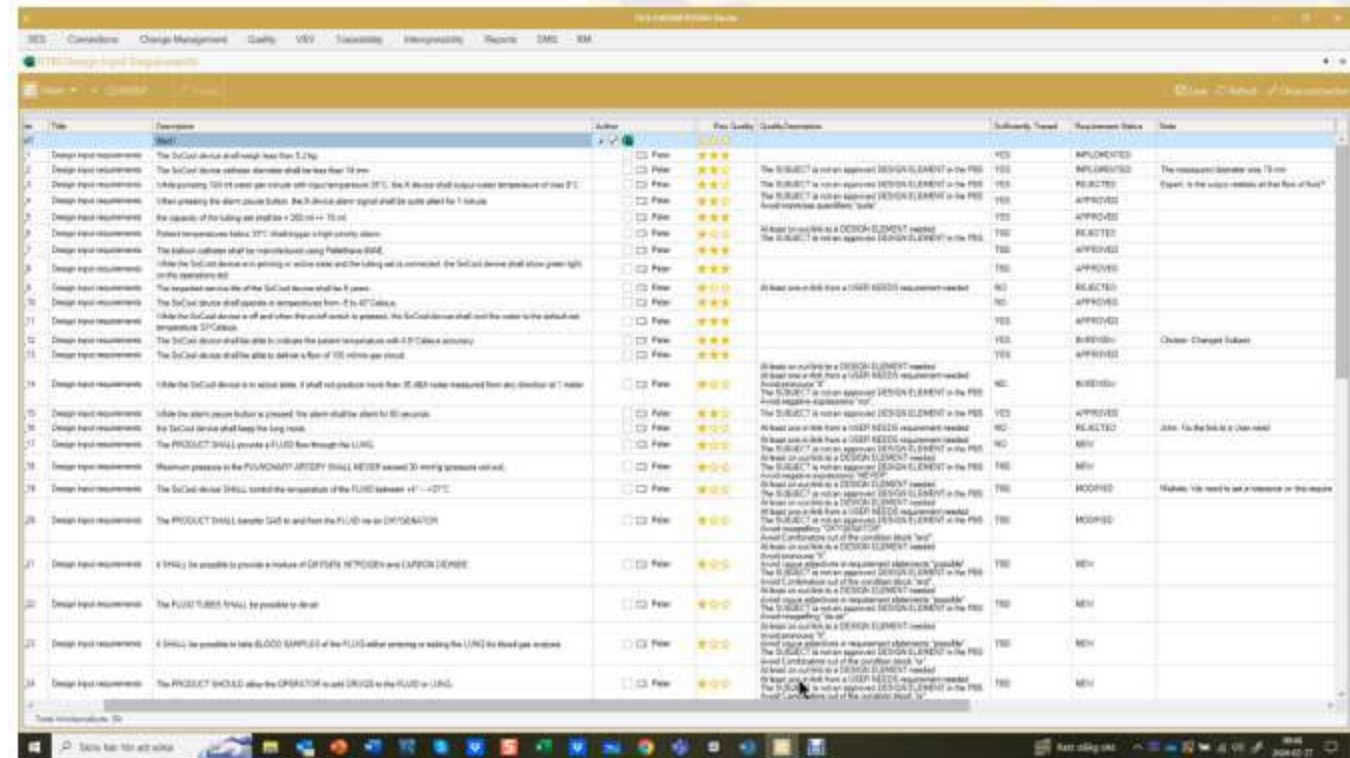
# Use Case #3 – Change management and connection baselines

## Manage a baseline (one connector)

- ▶ Create a baseline for a set of Design input requirement
- ▶ Compare this baseline to previously stored baseline

## Track changes

- ▶ Look at the changed Design input requirement
- ▶ Show versions of the same requirement

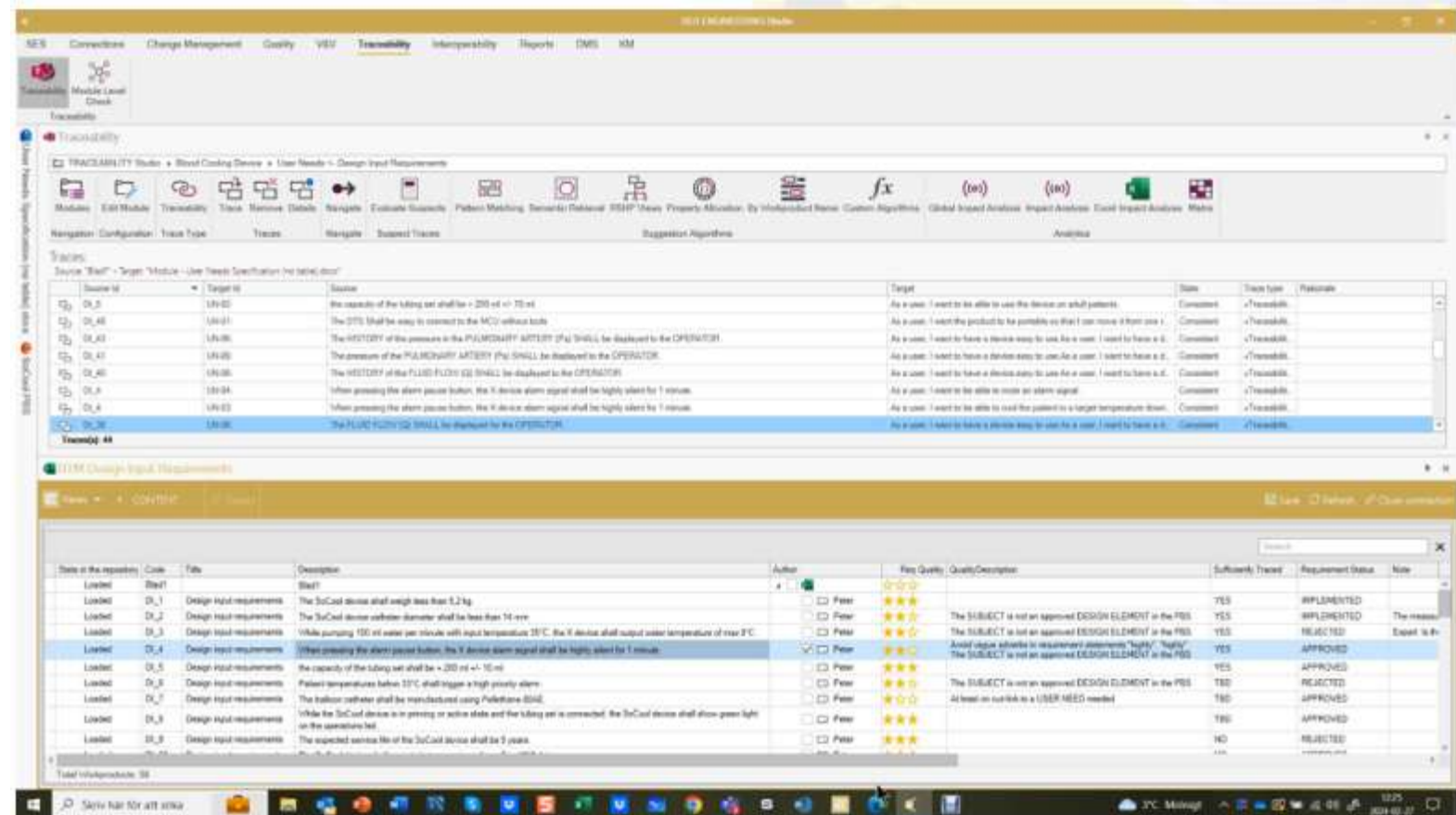


ID	Description	Author	Priority	Quality/Compliance	Subcategory	Trend	Requirement Status	State
1	The DC/DC device shall weigh less than 1.2kg.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
2	The DC/DC device maximum derating shall be less than 10 ppm.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
3	While operating, 100 mV error per channel with input temperature 25°C, the A device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
4	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
5	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
6	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
7	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
8	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
9	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
10	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
11	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
12	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
13	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
14	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
15	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
16	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
17	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
18	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
19	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
20	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
21	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
22	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
23	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED
24	While operating, the B device shall output voltage temperature of load 2%.	Peter	High	Compliant	YES	APPROVED	YES	APPROVED

# Use Case #4 – Traceability between connectors different work items

## The Traceability project

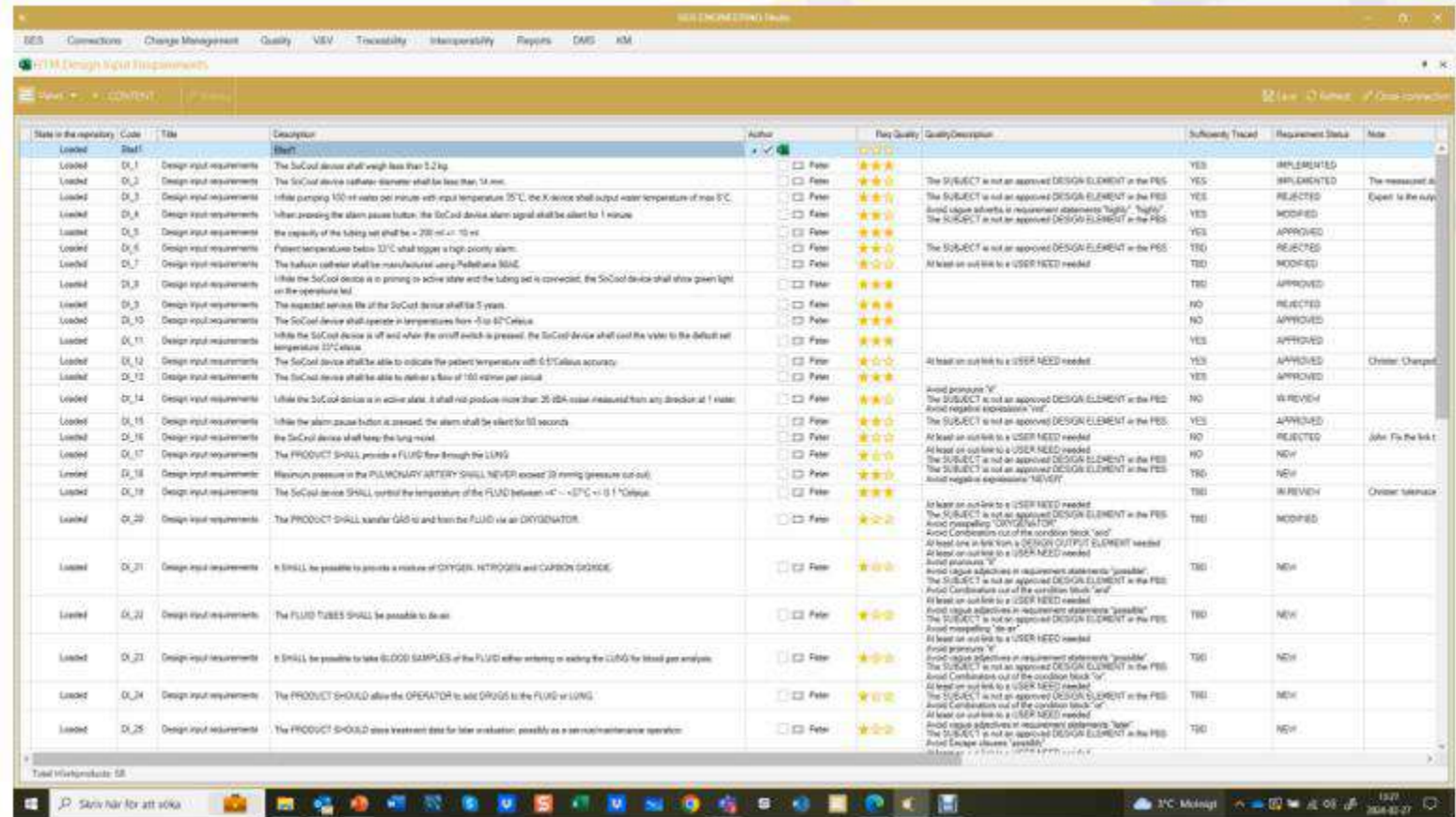
- ▶ Open all three connectors
- ▶ Open the traceability project
  - ▶ One module UN → DIR
- ▶ Make a trace
- ▶ Change one DIR
- ▶ Analyse suspect link



# Use Case #5 – Report generator

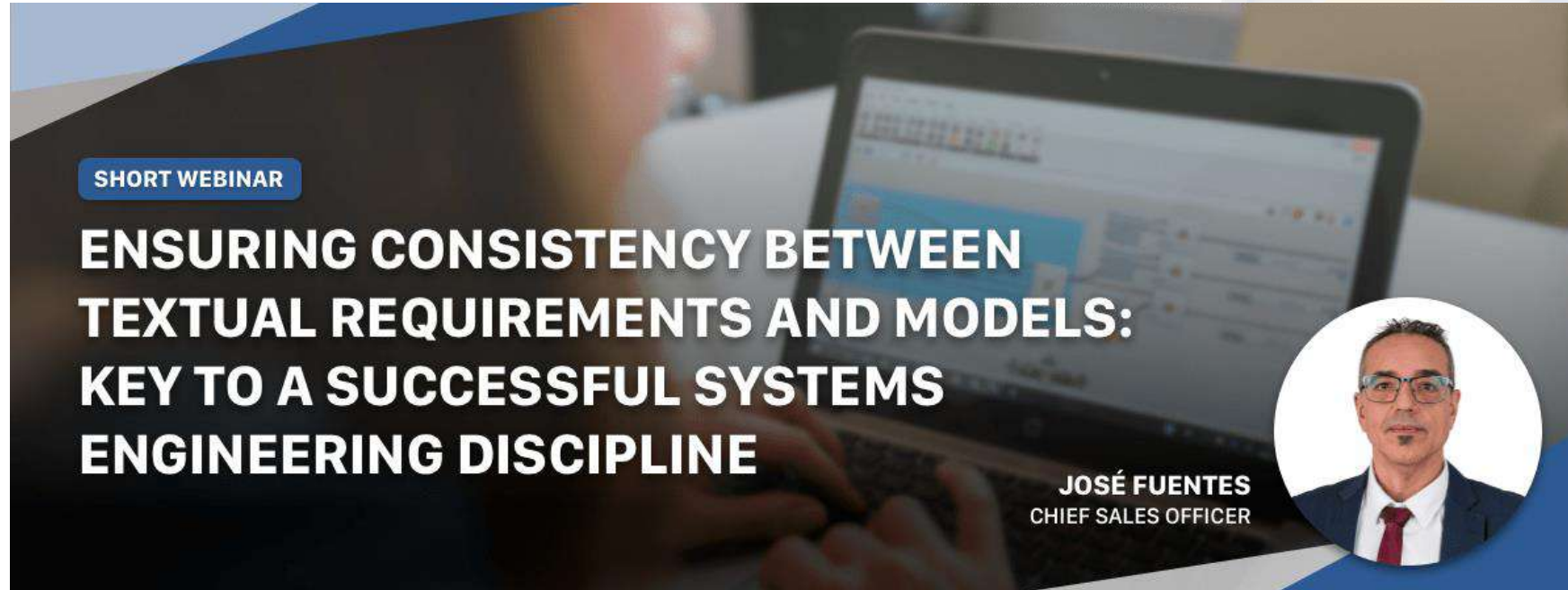
## The Report Generator

- ▶ Open the RTM report
- ▶ Show set up
- ▶ Run export and show result



State in the repository	Code	Title	Description	Author	Flag Quality	Quality Description	Sufficiently Traced	Requirement Status	Note
Loaded	DI_1	Design input requirements	The SoCool device shall weigh less than 1.2 kg.	Peter	★★★★		YES	IMPLEMENTED	
Loaded	DI_2	Design input requirements	The SoCool device catheter diameter shall be less than 14 mm.	Peter	★★★★	The SUBJECT is not an approved DESIGN ELEMENT in the PES	YES	IMPLEMENTED	The measurement
Loaded	DI_3	Design input requirements	While pumping 100 ml water per minute with input temperature 35°C, the X-device shall output water temperature of max 5°C.	Peter	★★★★	The SUBJECT is not an approved DESIGN ELEMENT in the PES	YES	REJECTED	Expert is the only
Loaded	DI_4	Design input requirements	When pressing the alarm pause button, the SoCool device alarm signal shall be silent for 1 minute.	Peter	★★★★	The SUBJECT is not an approved DESIGN ELEMENT in the PES	YES	MODIFIED	
Loaded	DI_5	Design input requirements	The capacity of the tubing set shall be <math>\geq 250\text{ ml}</math> or <math>10\text{ ml}</math>	Peter	★★★★		YES	APPROVED	
Loaded	DI_6	Design input requirements	Patent temperature below 33°C shall trigger a high-priority alarm.	Peter	★★★★	The SUBJECT is not an approved DESIGN ELEMENT in the PES	YES	REJECTED	
Loaded	DI_7	Design input requirements	The balloon catheter shall be manufactured using Pebax/PEBA SBAE.	Peter	★★★★	At least an out-link to a USER NEED needed	YES	MODIFIED	
Loaded	DI_8	Design input requirements	While the SoCool device is in priming or active state and the tubing set is connected, the SoCool device shall show green light on the operation led.	Peter	★★★★		YES	APPROVED	
Loaded	DI_9	Design input requirements	The expected service life of the SoCool device shall be 5 years.	Peter	★★★★		NO	REJECTED	
Loaded	DI_10	Design input requirements	The SoCool device shall operate in temperatures from <math>-10\text{ to }62\text{ }^\circ\text{C}</math>	Peter	★★★★		NO	APPROVED	
Loaded	DI_11	Design input requirements	While the SoCool device is off and when the on/off switch is pressed, the SoCool device shall cool the water to the default set temperature 32°Celsius.	Peter	★★★★		YES	APPROVED	
Loaded	DI_12	Design input requirements	The SoCool device shall be able to indicate the patient temperature with 0.1°Celsius accuracy.	Peter	★★★★	At least an out-link to a USER NEED needed	YES	APPROVED	Change: Change
Loaded	DI_13	Design input requirements	The SoCool device shall be able to deliver a flow of 100 ml/min per adult.	Peter	★★★★		YES	APPROVED	
Loaded	DI_14	Design input requirements	While the SoCool device is in active state, it shall not produce more than 20 dB(A) noise (measured from any direction at 1 meter).	Peter	★★★★	At least an out-link to a USER NEED needed	NO	IN REVIEW	
Loaded	DI_15	Design input requirements	While the alarm-pause button is pressed, the alarm shall be silent for 60 seconds.	Peter	★★★★	The SUBJECT is not an approved DESIGN ELEMENT in the PES	YES	APPROVED	
Loaded	DI_16	Design input requirements	The SoCool device shall keep the lung moist.	Peter	★★★★	At least an out-link to a USER NEED needed	NO	REJECTED	John: Fix the link t
Loaded	DI_17	Design input requirements	The PRODUCT SHALL provide a FLUID flow through the LUNGS	Peter	★★★★	The SUBJECT is not an approved DESIGN ELEMENT in the PES	NO	NEW	
Loaded	DI_18	Design input requirements	Maximum pressure in the PULMONARY ARTERY SHALL NEVER exceed 30 mmHg (pressure cut-out)	Peter	★★★★	The SUBJECT is not an approved DESIGN ELEMENT in the PES	YES	NEW	
Loaded	DI_19	Design input requirements	The SoCool device SHALL control the temperature of the FLUID between <math>-1\text{ }^\circ\text{C}</math> – <math>+37\text{ }^\circ\text{C}</math> or <math>0\text{ }^\circ\text{C}</math>	Peter	★★★★	At least an out-link to a USER NEED needed	YES	IN REVIEW	Change: Release
Loaded	DI_20	Design input requirements	The PRODUCT SHALL transfer GAS to and from the FLUID via an OXYGENATOR.	Peter	★★★★	At least an out-link to a USER NEED needed The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "and" At least one in-link from a DESIGN OUTPUT ELEMENT needed At least an out-link to a USER NEED needed Avoid constraints "or" Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "and" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "and" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "and" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "and"	YES	MODIFIED	
Loaded	DI_21	Design input requirements	It SHALL be possible to provide a mixture of OXYGEN, NITROGEN and CARBON DIOXIDE.	Peter	★★★★	At least an out-link to a USER NEED needed The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link from a DESIGN OUTPUT ELEMENT needed At least an out-link to a USER NEED needed Avoid constraints "or" Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "and" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "and"	YES	NEW	
Loaded	DI_22	Design input requirements	The FLUID TUBES SHALL be possible to drain	Peter	★★★★	At least an out-link to a USER NEED needed The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link from a DESIGN OUTPUT ELEMENT needed At least an out-link to a USER NEED needed Avoid constraints "or" Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "and" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "and"	YES	NEW	
Loaded	DI_23	Design input requirements	It SHALL be possible to take BLOOD SAMPLES of the FLUID either entering or exiting the LUNGS for blood gas analysis.	Peter	★★★★	At least an out-link to a USER NEED needed The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link from a DESIGN OUTPUT ELEMENT needed At least an out-link to a USER NEED needed Avoid constraints "or" Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "and" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "and"	YES	NEW	
Loaded	DI_24	Design input requirements	The PRODUCT SHOULD allow the OPERATOR to add DRUGS to the FLUID or LUNGS.	Peter	★★★★	At least an out-link to a USER NEED needed The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link from a DESIGN OUTPUT ELEMENT needed At least an out-link to a USER NEED needed Avoid constraints "or" Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "and" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "and"	YES	NEW	
Loaded	DI_25	Design input requirements	The PRODUCT SHOULD store treatment data for later evaluation, possibly as a non-maintenance operation.	Peter	★★★★	At least an out-link to a USER NEED needed The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link from a DESIGN OUTPUT ELEMENT needed At least an out-link to a USER NEED needed Avoid constraints "or" Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "and" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "possible" The SUBJECT is not an approved DESIGN ELEMENT in the PES Avoid Constraints out of the operation track "or" At least one in-link to a USER NEED needed Avoid logical adjectives in requirement statements "and"	YES	NEW	





SHORT WEBINAR

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