



Improving Quality (IQ) cluster

Supply Base Risk Management: Extend your Organization

Engage with your supplier!

Supply Base Risk Management: Extend your Organization

What's in it for me?



Possible hazards



Definitions

Risk: combination of the probability of occurrence of harm and the severity of that harm [ISO/IEC Guide 51]

Safety: the state of being protected from recognized hazards that are likely to cause harm [ISO/IEC Guide 51]

Why

- 88% interruption are caused by technical or human factors
- 74% of the companies experience at least 1 serious problem in the chain every 12 months
- Impact of this risk is quantified as a supplier's risk
- These risks can easily exceed millions of euros

AS 9100 D par 8.1.1

4.1 Understanding the Organization and Its Context

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. ...

AI-GRESS-L40211 - AI-GRAMS-L400303 – IPCA - IPCA +

Set up a process analysis to build the industrial process flow chart. For every process step: production rate, On Time Delivery (OTD), lot size and lead time, inventory, number of resources, available time, utilisation and efficiency, bottleneck identification

ISO 13485:2016

7.1 The organization shall document one or more processes for risk management in product realization.

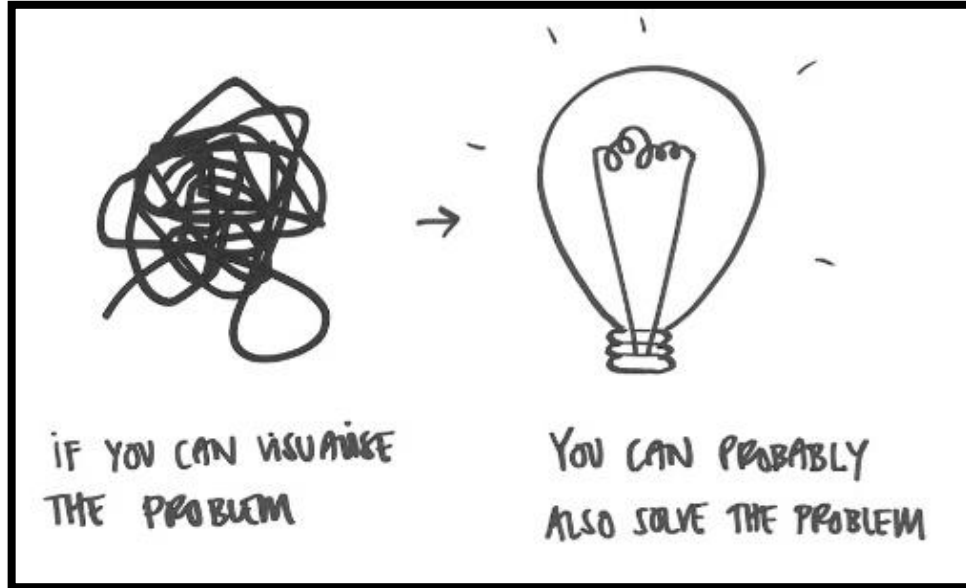
7.4.1 The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be:

..

d) proportionate to the risk associated with the medical device.

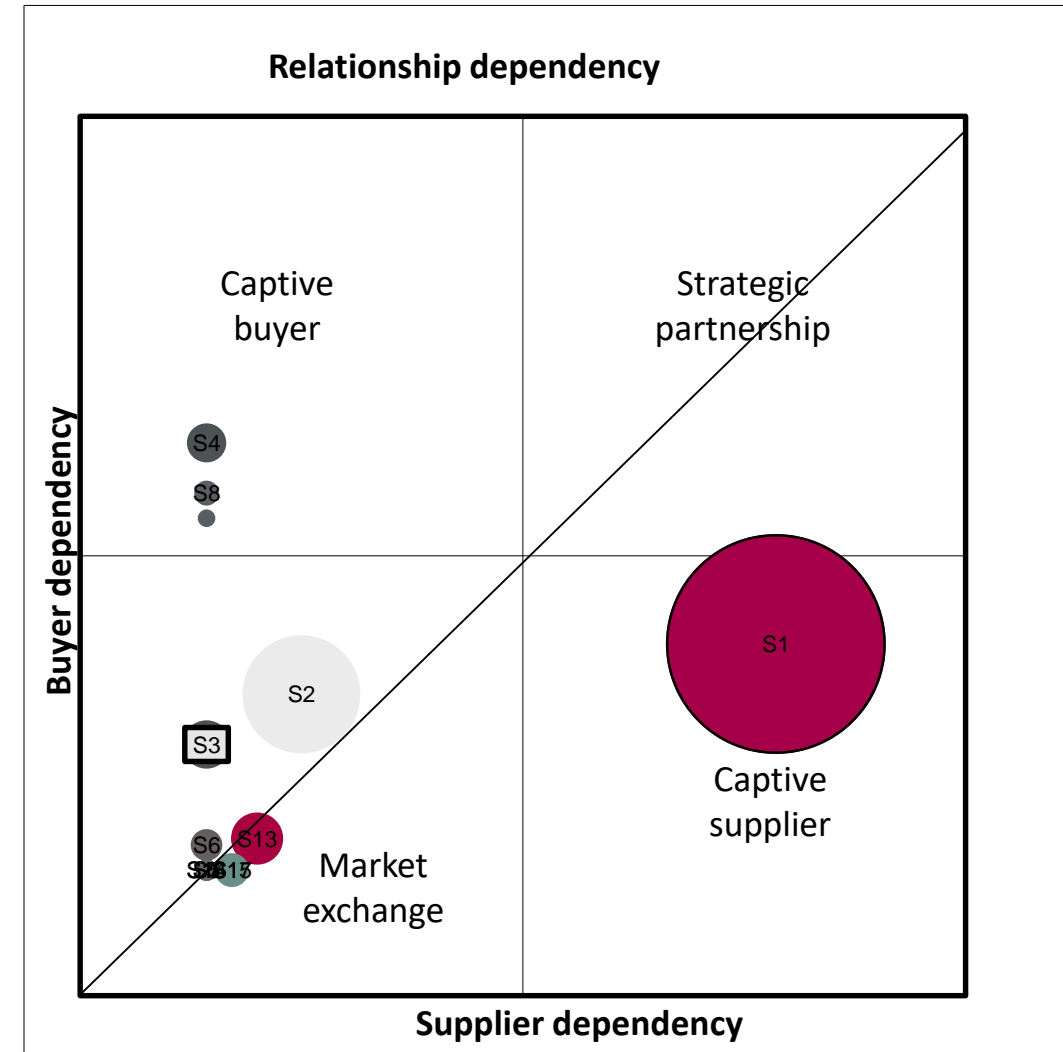
Identification of possible bottlenecks because this is a severe risk with major impact on our suppliers, our resources, stakeholders and customers.

Methodology



Visualization can help with

- Create insight
 - value adding activities
 - efficiency of activities
- -> insight as enabler for new behavior
- Cooperation as tool to build support and reduce resistance
- Identify failure modes and their effects for urgency (priority)



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The application





NAG – *Netherlands Aerospace Group* **Risk management & Extention of the org.**

The Engage Process Suite

November 5th, 2019

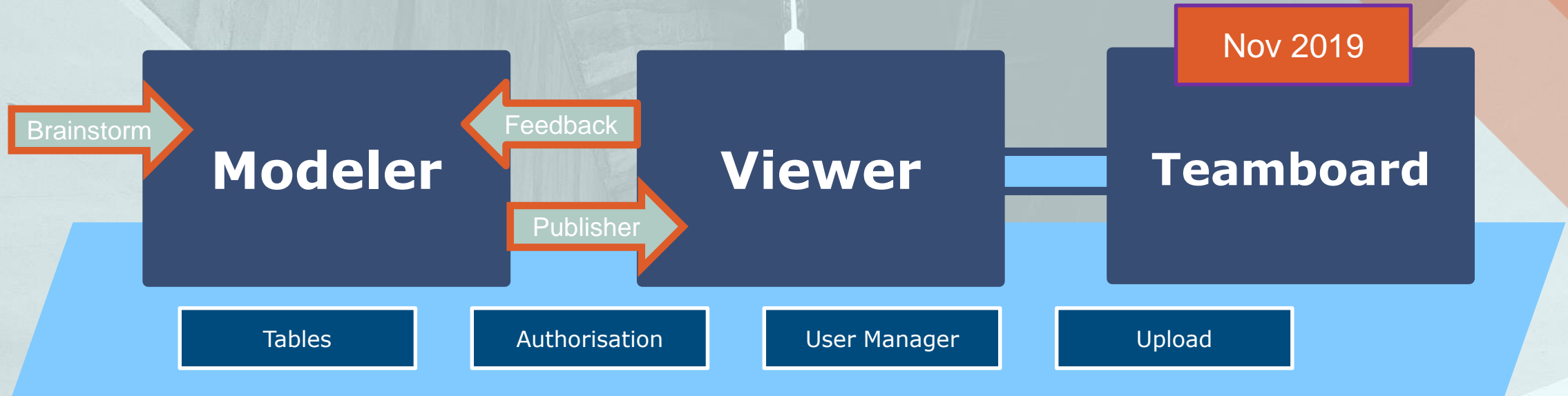
Ted Twaalfhoven

Dick Langeveld

Who is Engage Process?

Extensive process management platform

"Getting your people deeply involved in critical issues"

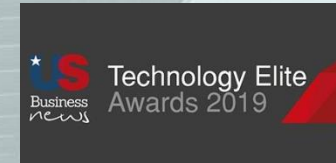


Fields

- ✓ Control
- ✓ Improvement
- ✓ Compliance
- ✓ Handbook
- ✓ Agile
- ✓ Transformation

Who?

- ✓ Manufacturing
- ✓ Trade/ Logistics
- ✓ Financials
- ✓ Airports
- ✓ Cities
- ✓ Housing
- ✓ Healthcare



The challenge of transformation and change

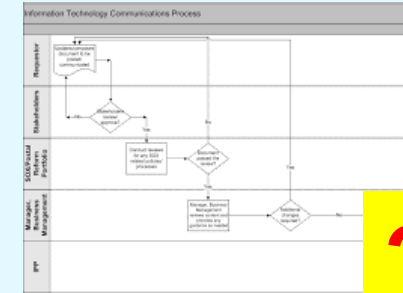
70%

Does not deliver on expectations

(McKinsey, 2018)

Culture drives adoption
Every employee participates
Organisational agility
Processes are at the core

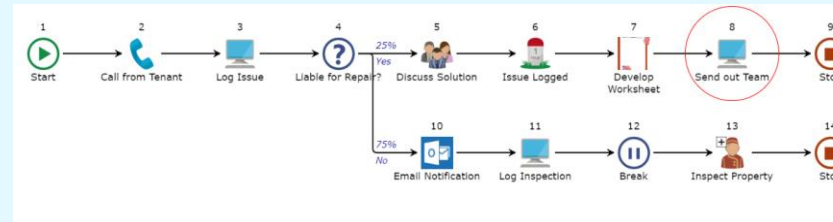
Our philosophy



Uhhhh...

Explore your processes with your teams !

P & Q & D



Covering all fields

- ✓ Control
- ✓ Improvement
- ✓ Compliance
- ✓ Handbook
- ✓ Agile
- ✓ Transformation

Comic
Book

Process
Logic
Engine

Switch
View®

Hide/
Show®

Calc&
Compare

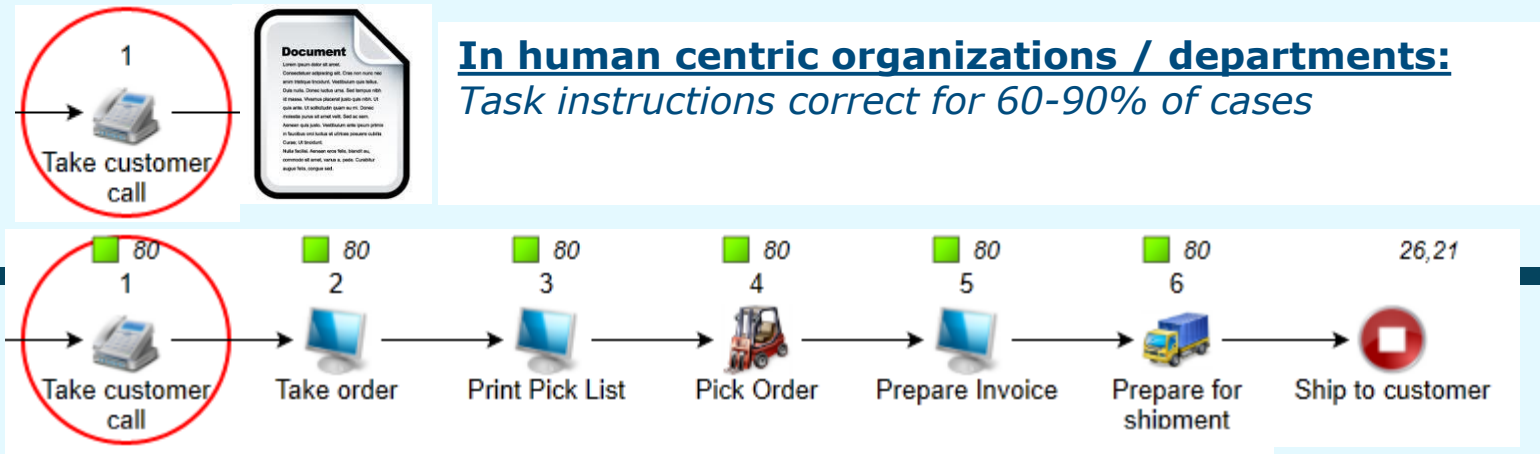
Team
board

Continuously
Improve

Ease of
SaaS

Only the team knows the real process

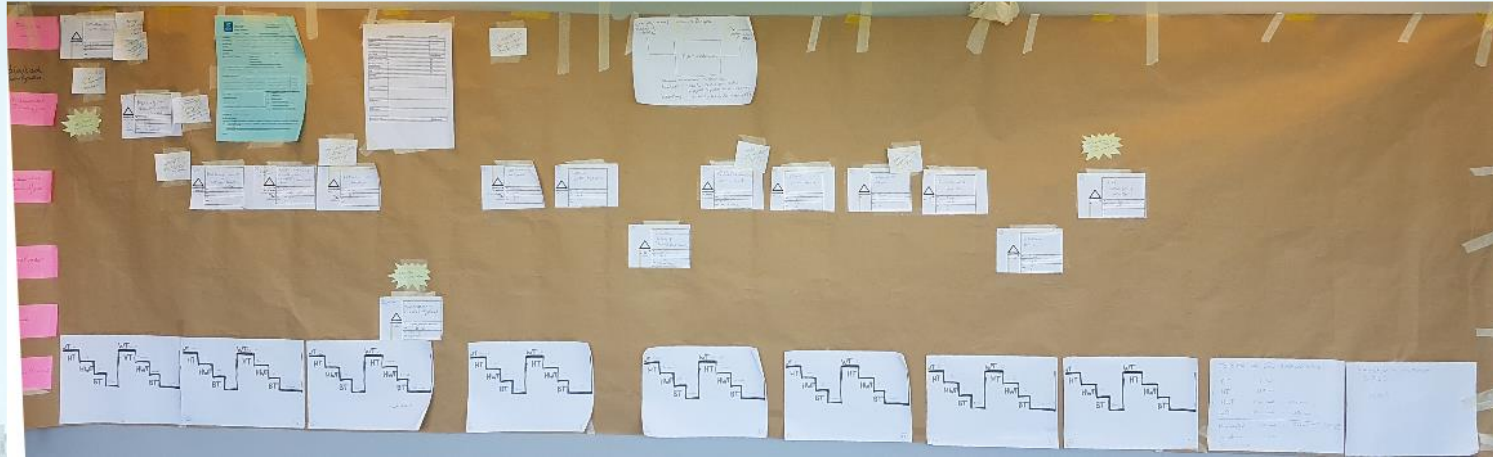
Exceptions and "The hidden factory"



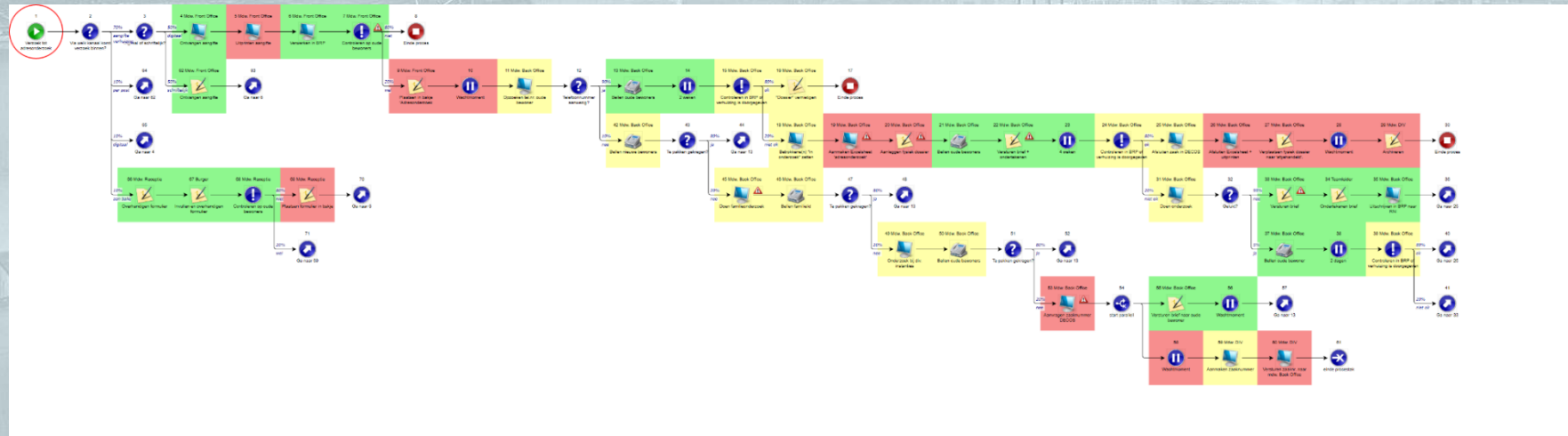
Sum of exceptions is often greater than number in happy flow

Does management / QA know the exceptions?

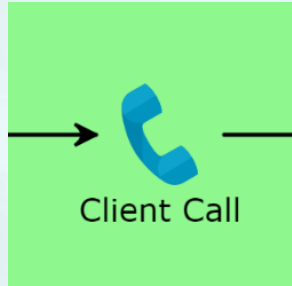
Do employees know what regulations and instructions to use in case of a sporadic exception?



Example: What is the true process?



Example: Handling Complaints



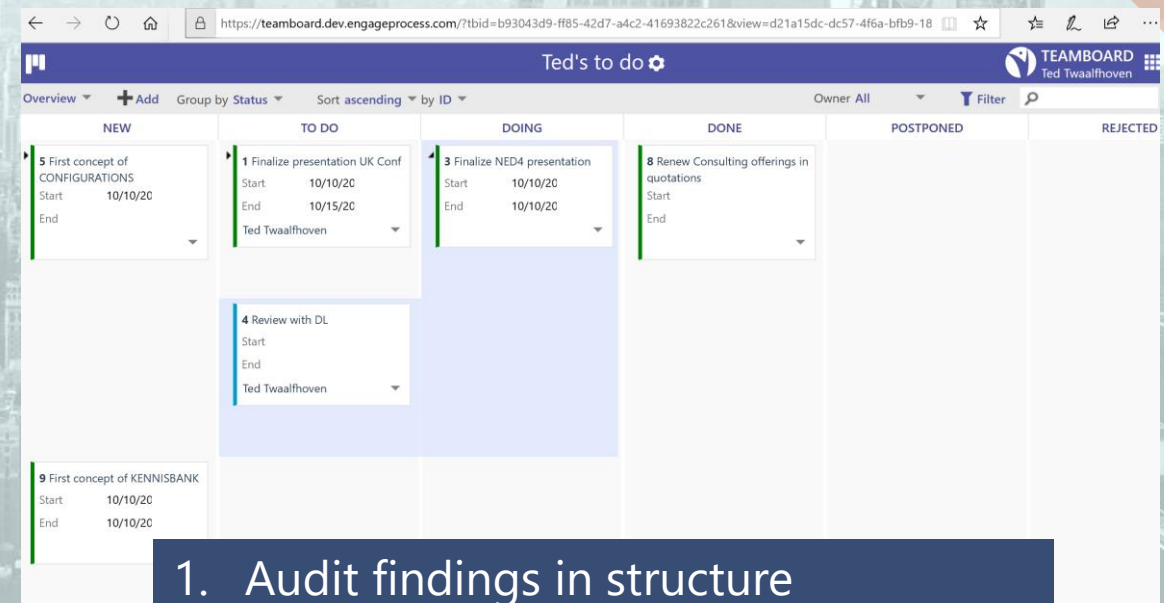


2018: Compliance and Risk Management



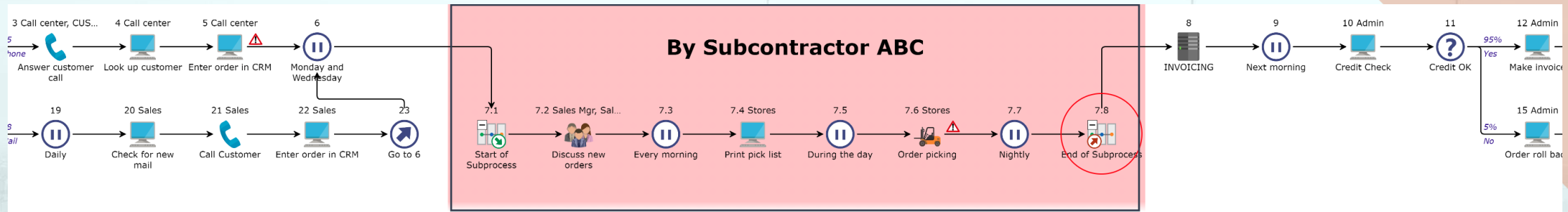
1. Risk reports
2. FMEA
3. Regulations linked to handbook!

2019: Teamboard



1. Audit findings in structure
2. Findings linked to processes & steps
 - corrective actions
 - improvements

Supply chain.....



1. What do you want Supplier to do – Which steps!!
➔ Map, discuss and explore the process
2. Know and manage exceptions.
3. Know where which regulations apply.
4. Work constructively and jointly on improvements.
➔ Focussed on what's important for the (internal) client.
5. Focus on shared critical parameters and where they have bottlenecks.

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Stakeholders



Procurement

[*Leverancier B*]

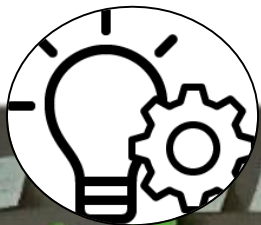
[*Leverancier A*]



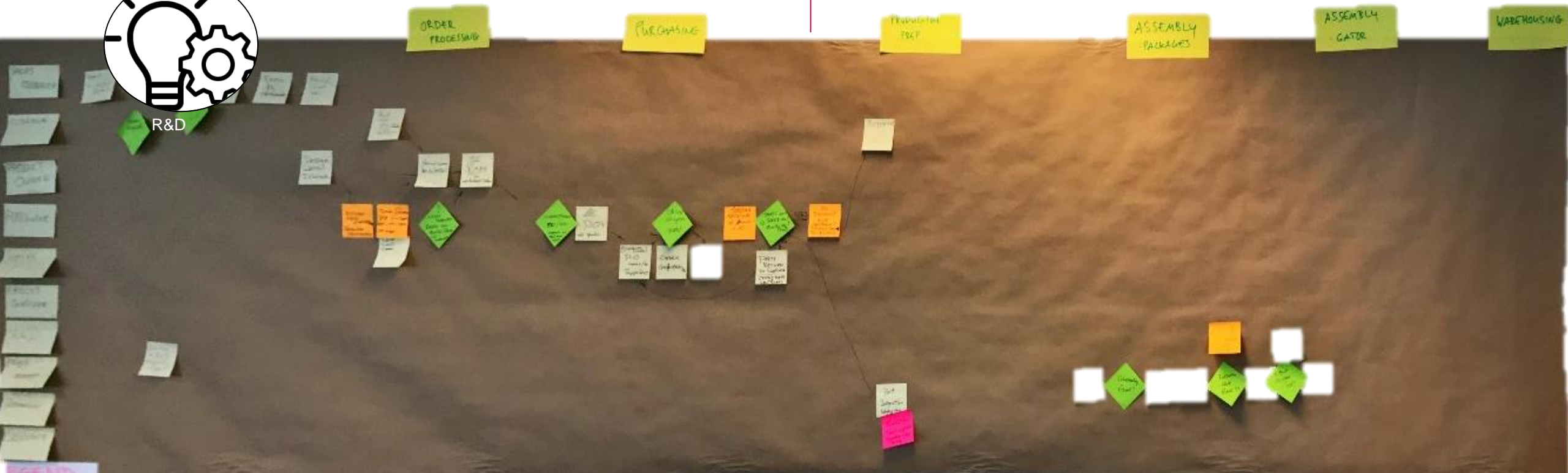
Quality



Production

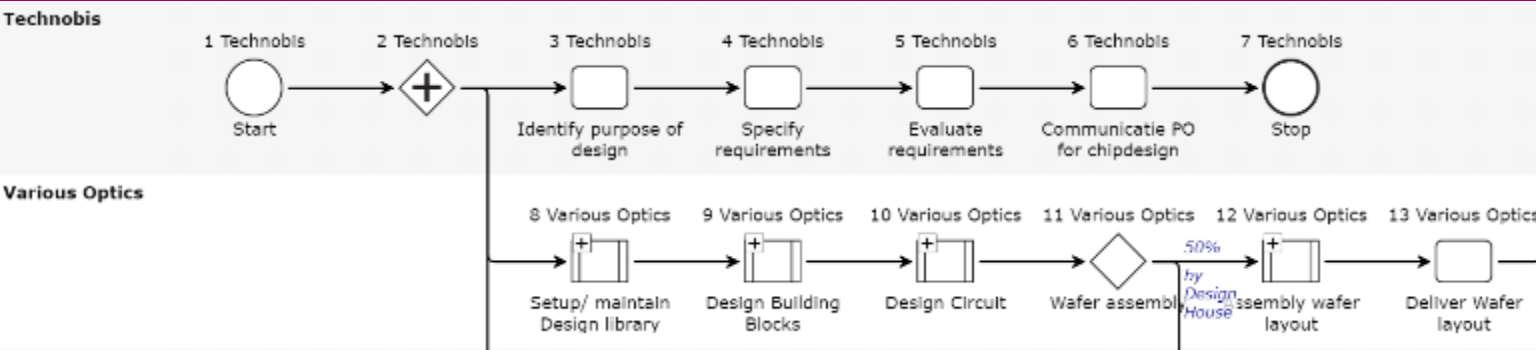


R&D



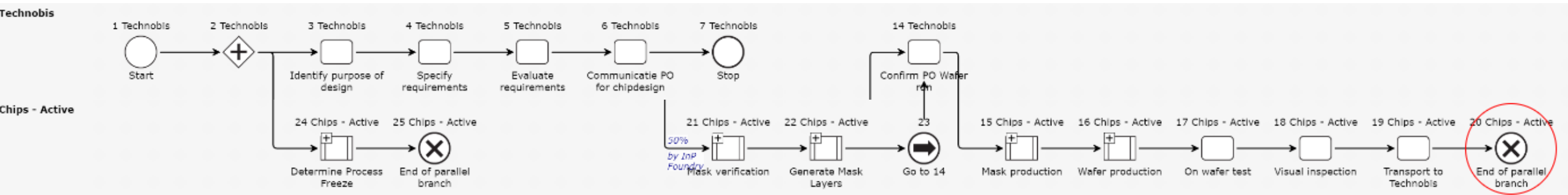
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From toplevel!

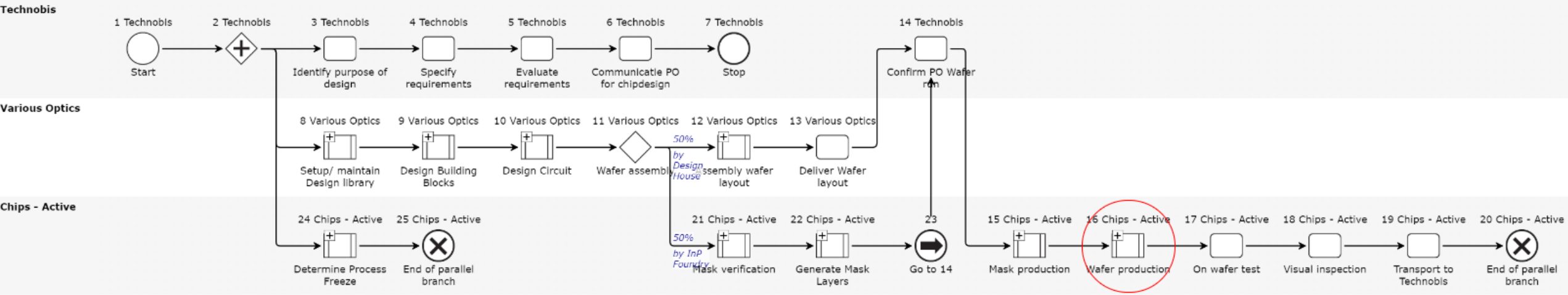


Perception:

- We order a design
- We order a product



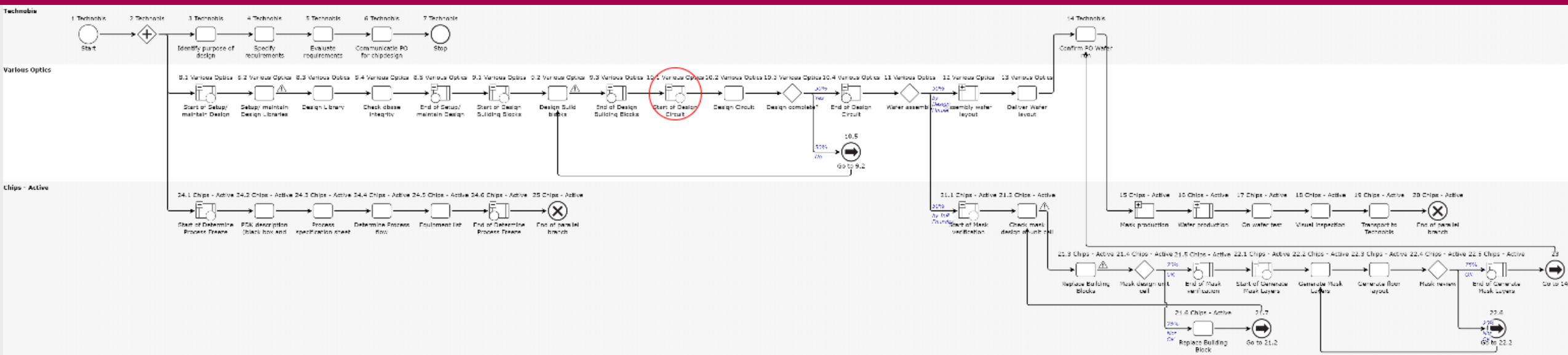
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Insight | Lessons learnt

- That's a lot of dependancies!
- Didn't know that this kind of information was so important for your job?

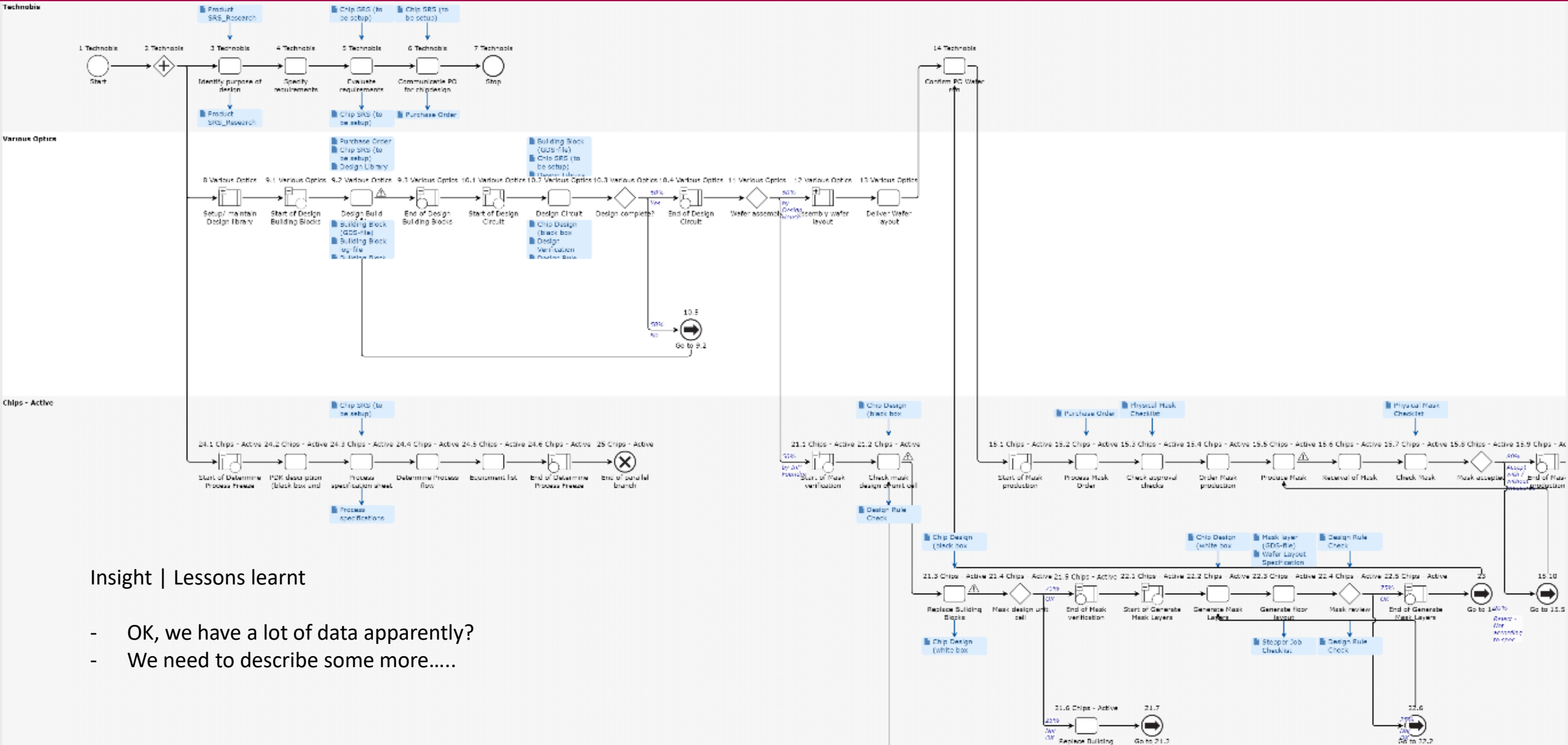
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Insight | Lessons learnt

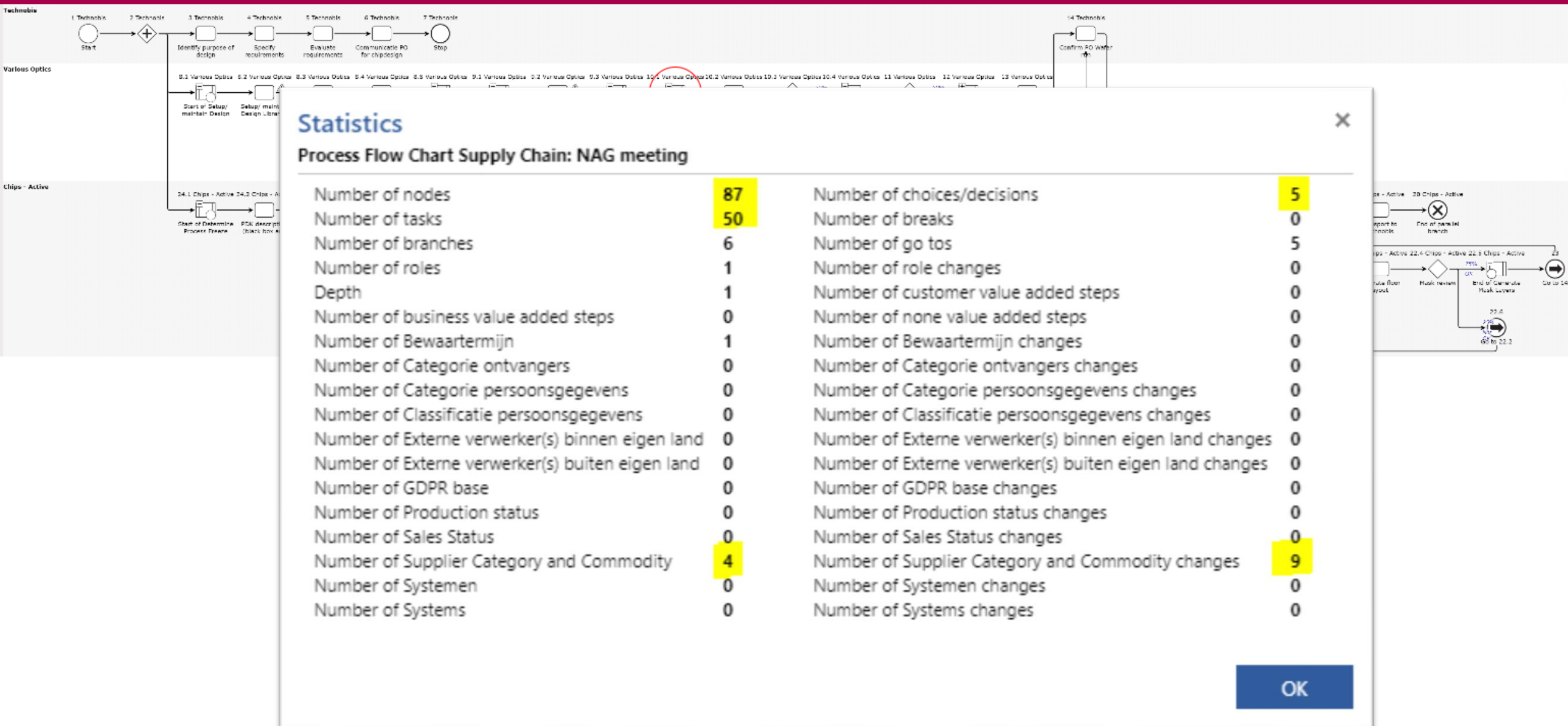
- Thats a lot of checks! Do you log the results?
- Huh! You outsource some steps?
- Oh. If some machines have failures you can perform the activitiy manually?

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Into the smallest details...



Discuss impact and solutions

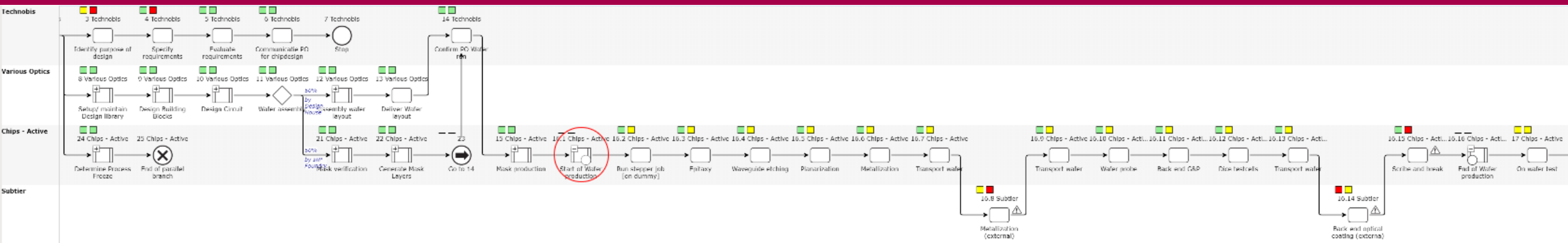
[illegible]

Insight | Lessons learnt

- I have never realised how many mistakes can occur doing that. And it's effect!

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Think positive



Insight | Lessons learnt

- OK. Lead time is much longer than the processing time. What can we do to help you reduce the lead time?
- OEE and mitigation measures lead to increased LT and PT by 30%! How often is equipment down?

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Lessons learnt

- Mutual understanding in the supply chain
- Nothing is what it seems
- New customer- relationships were identified
- Knowledge about the ecosystem was shared and the bar was raised
- Company specific decisions were discussed within (parts of) the supply chain
- Co-creation regarding specs, manuals, test reports, etc

And

- Comparing different companies performing “the same step” is made easier

Success factors



Identification of a challenge



Confront the challenge [the brutal facts]



Repeat your message and objectives



White AND Blue collar, technical and business must be involved



Management must take responsibility: join and facilitate





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