Integrating hygienic Entities

What could **you** get from Document 34?

- Two WG-teams + several reviewers

- 80 pages

In 20 minutes

Themes of Presentation

A. Backbone: flowcharts: phases + interdependencies + sequencing
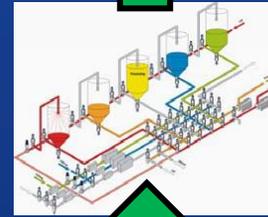
B. *Meta*-knowledge is shared, for example:

    a. About missing knowledge
    b. About hidden knowledge
    c. About some common types of failure
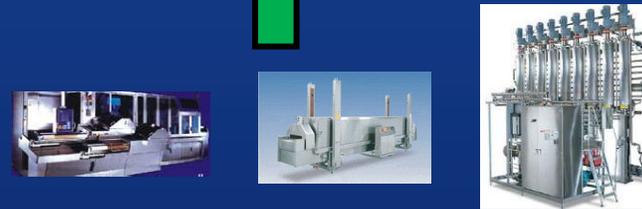   d. Content in the appendices

Area/ Site

Line

Unit

Module

Part

Material of Construction

Fe C Cr Ni Mo Mn N- alloy

polymer, oligomer, monomer

Whole factories or enterprises can fail if any one of the Integrations is faulty

For example, a seal-design,

a verification-step, information,

instruction, cleaning-procedure

Integrating hygienic Entities: Life-cycle

How to apply the existing EHEDG-guidelines throughout:

1. Designing
2. Building
3. Operating
4. Cleaning
5. Maintaining
6. Shutting-down
7. Dismantling
8. Re-commissioning
9. Re-selling

1. "The process of combining or arranging two or more entities to work together, whilst eliminating or minimizing hygiene-risks"

   Hygiene-risks?

2. But the *opposite* is often true.

3. Entities are often combined in way that *creates* hazards

Integrating hygienic Entities: Focus

A. A hygiene-risk is a risk to *more* than food-safety alone

B. It is a risk to **any** of the potential benefits of hygienic design:

a. Water-conservation
b. Energy-conservation
c. Reduced need for cleaning-chemical
d. Reduced need for cleaning-labour
e. Maximisation of capacity (faster turnround)
f. Reduction in required facility-"footprint"
g. Reduced spares-inventory
h. Simplified maintenance
i. Simplified troubleshooting
j. Simplified equipment/process-layout (e.g. hygiene-zones)
k. Simpler process-management
l. Legal/regulatory compliance
m. Safer food
n. Safer personnel
o. Better quality-conformity
p. Reduced *cost of non-conformity (lost or rejected product*, breakdowns or legal costs)*
q. *Stronger food-defence*
r. *Etcetera, etcetera……….*

1. GFSI-accredited audit-models address management of:

   1. food-safety
   2. *Food-quality*
   3. *food-defence*

CCPs and Hygienic Design (HD) in *food-safety alone*

| Requirement	CCPs	HD
Product safety	✓	
Overall product quality		✓
R&D failure-rate		✓
R&D false results		✓
R&D delays		✓
Required R&D facility-size		✓
Required R&D capital-investment		✓
Product failure-rate/rejections		✓
Investigational costs and time		✓
Water-usage/waste *during cleaning*		✓
Product-loss(washings) *during cleaning*		✓
Chemical usage/waste *during cleaning*		✓
Energy-usage/waste *during cleaning*		✓
labour usage/waste *during cleaning*		✓
Environmental impact		✓
Down-time *during cleaning*		✓
Up-time /productivity		✓
Required production-"footprint"		✓
Required capital-investment		✓
Reliability/consistency of production & product		✓
Legal compliance	food safety only ✓	✓
Environment, Corporate and Social Responsibility (ECSR)	food safety only ✓	✓
Profitability	✓	✓

CCPs act as backstops
and can compensate for earlier
HD-failings, - *up to a point!*

**HD is a *prerequisite* at each CCP and
For any subsequent process-step,
invariably primary packing.**

ALARP and AFAP

Dr Roland Cocker

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EUROPEAN HYGIENIC ENGINEERING & DESIGN GROUP

Overview of integrating hygienic Entities: (V-model)
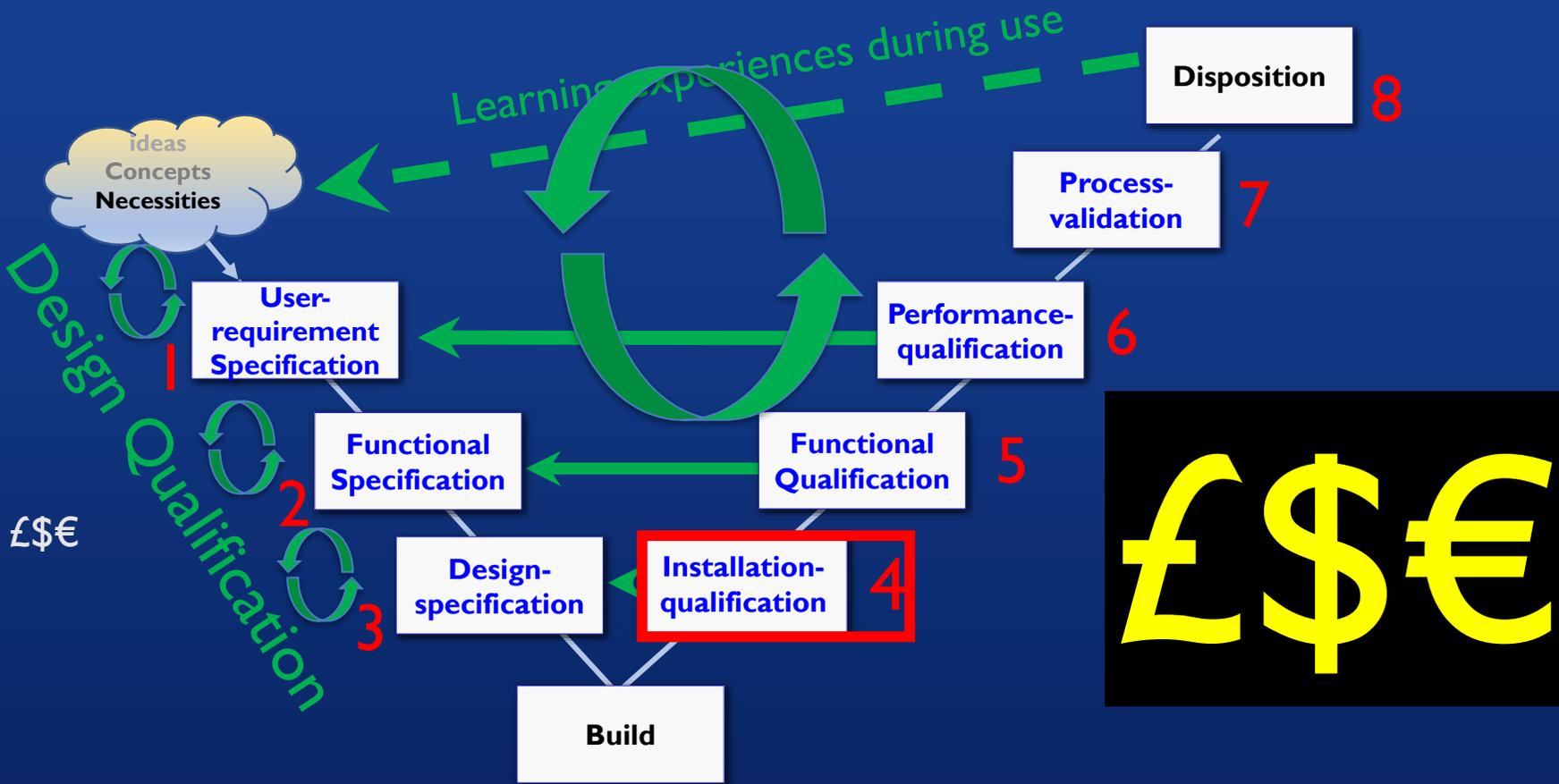
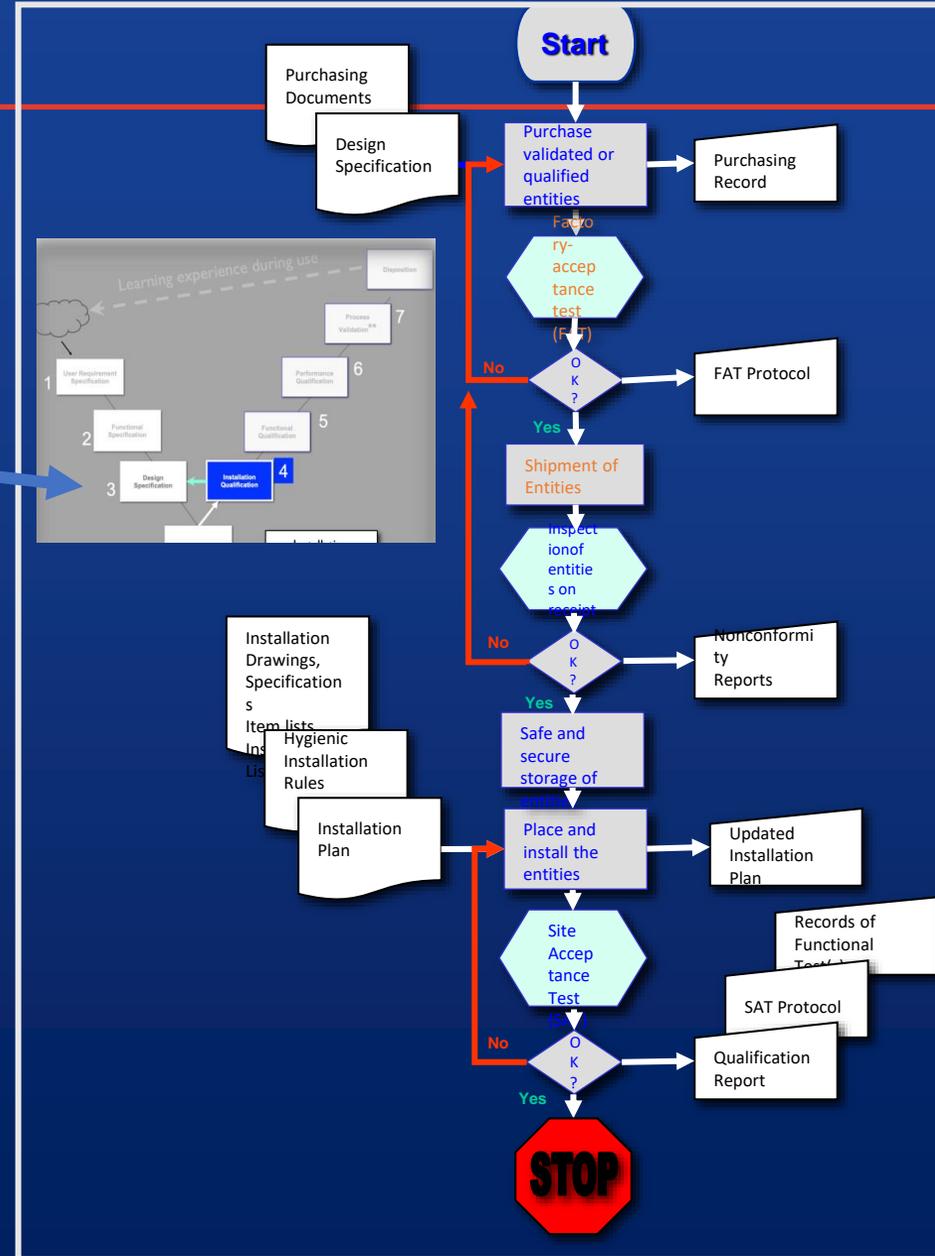# Details of each Phase (4a)

Orientation-guide
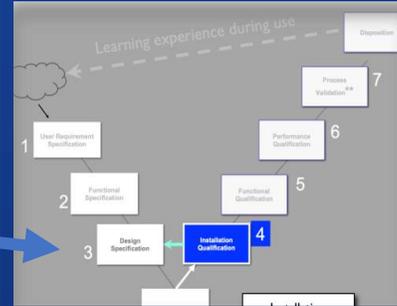
Assigned entities

assigned to a *specific combination* of location, raw material(s), process(es), product(s), operation(s), staffing, automation, etcetera.
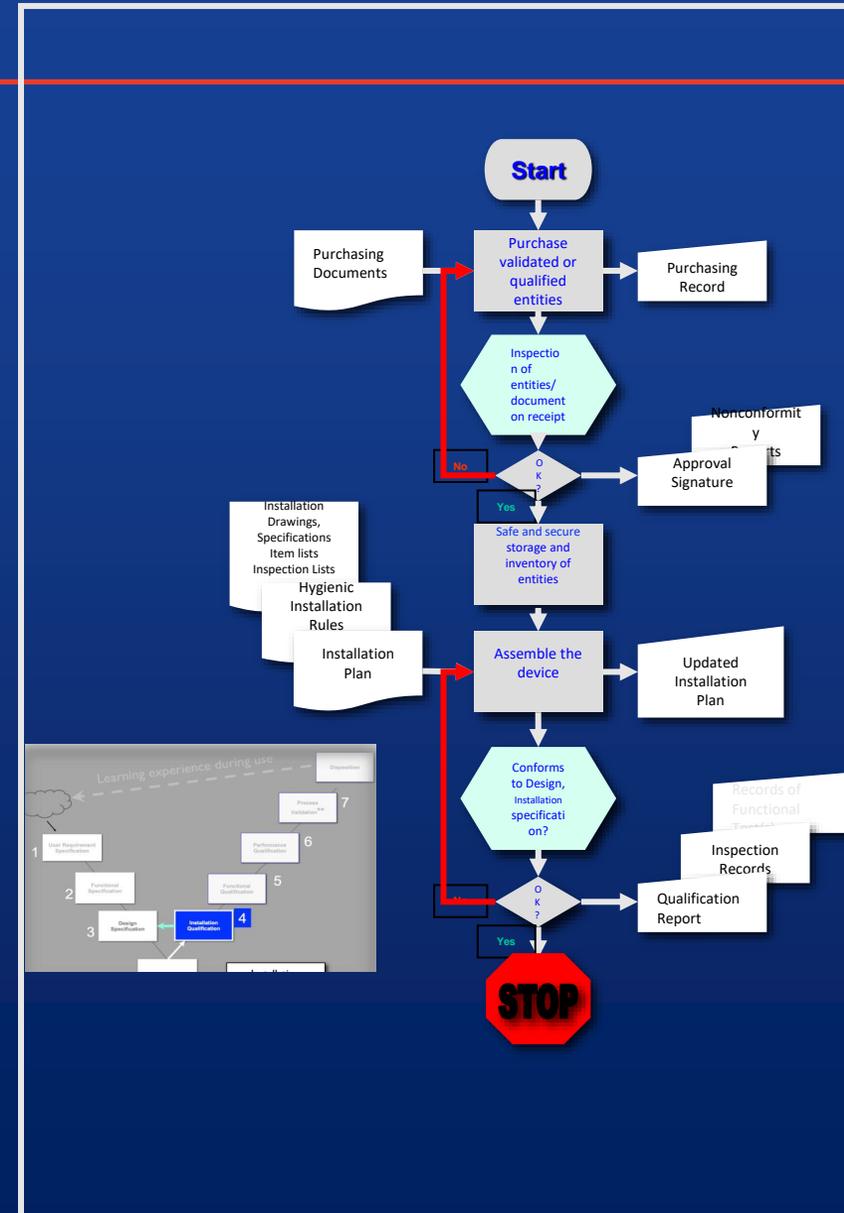
Dr Roland Cocker   EHEDG World Congress 2022 - Munich, Germany.   ©Cocker/EHEDG   11

Details of each Phase (4b)

Unassigned entities

 e.g. entities on the market, not *assigned* to a *specific combination* of location, raw material(s), process(es), product(s), operation(s), staffing, automation, etcetera.

- Documented verification of repeatability

- Probationary period of scrutiny
  - Food-safety and -quality (CCPs, PRPs, statistical process controls, pest-control, internal and third-party audits)
  - throughput-rates
  - mean times between cleaning-shutdowns
  - cleaning-durations
  - cleaning-effectiveness
  - waste-treatment demands or charges
  - maximum downtime for hygiene-related maintenance (cleaning, inspection and maintenance)
  - specified product parameters
  - building- and utilities-performance

- Achievement of a contracted minimum number of successful validation-runs?

- Joint acceptance before handover (clear URS/SRS/contract)

Prototype "checklists"
-Unassigned!

Meta-advice: Appendices A to I
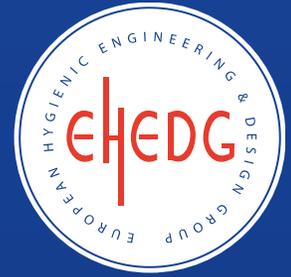
how the workflow can be applied to a range of projects.

Appendix A: Designing and Producing an unassigned Hygienic Pipe-coupling
Appendix B: Assigning a hygienic Coupling into a Unit
Appendix C: Developing automation-systems for food-processing
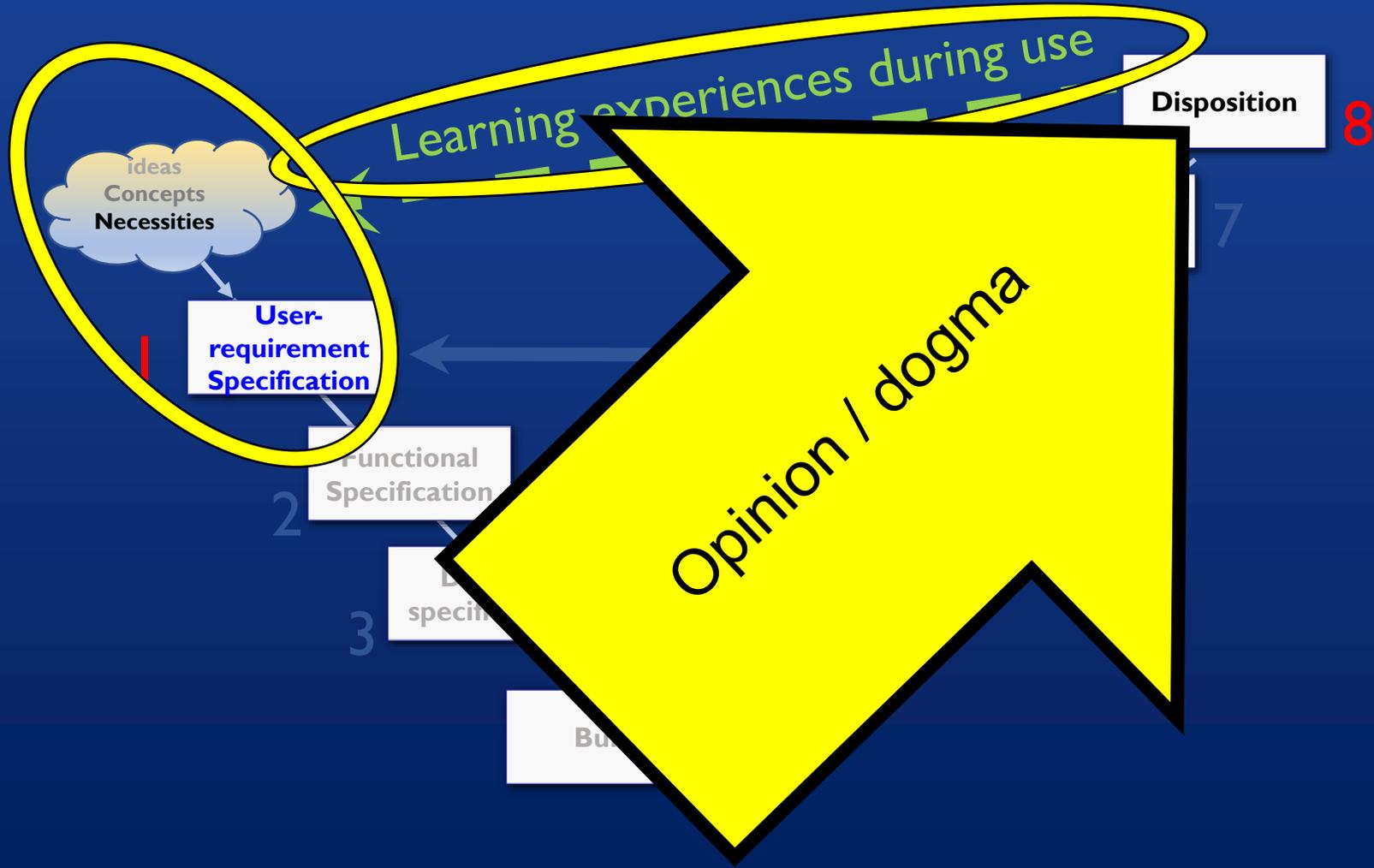Appendix D: Performing Building-projects

Appendix E: Explanation of Flowchart-conventions

new insights

Appendix F: Acceptable Standards of Risk: ALARP and AFAP
Appendix G: Dealing with Legacy-systems
Appendix H: Costing of Decisions between *renovate* and *build-new*

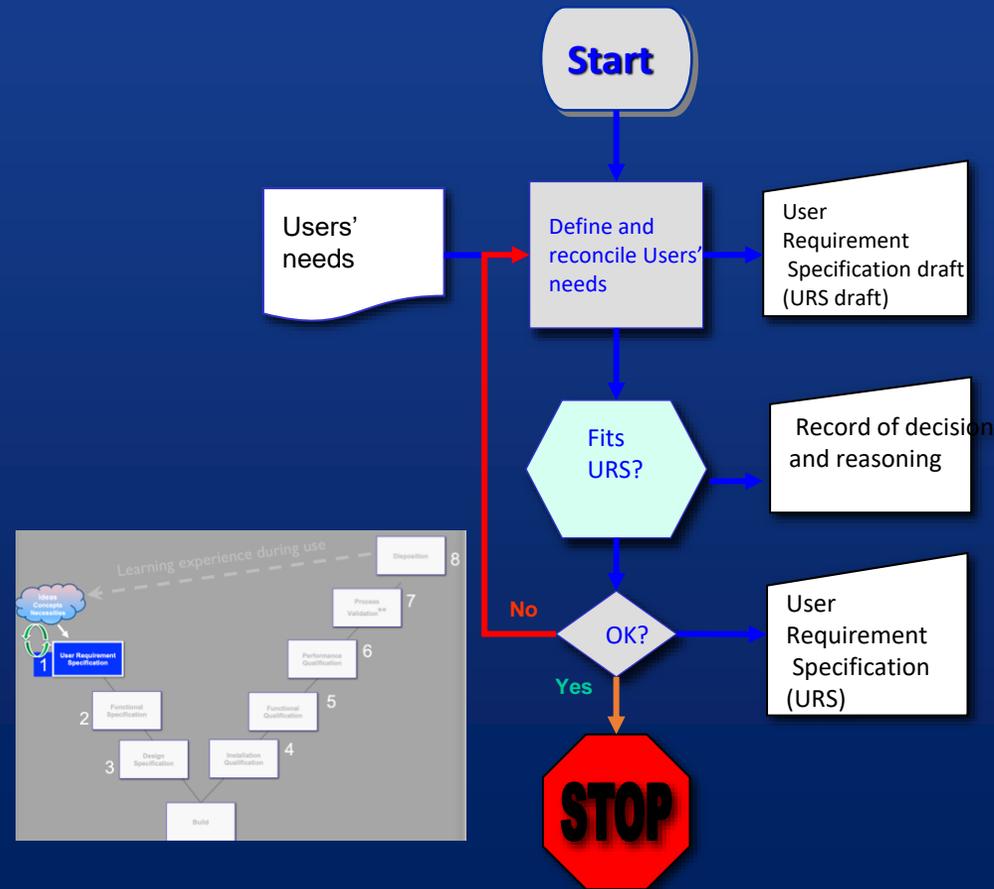Appendix I: Training and Qualification of Personnel

1. User/Stakeholder-requirements Specification

Integrating hygienic Entities: *missing* Information

Omission of stakeholders *in the design-specification!*

Undocumented Know-how ("forgot to mention", continuity)

"real-time repairs" (heuristics versus software-responses)

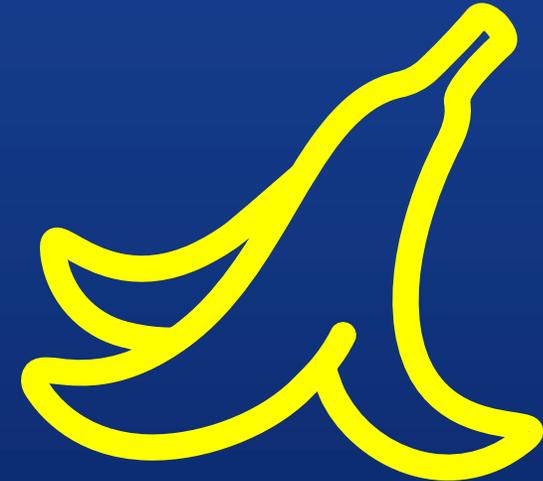Predictable changes? (business plans, regulatory, technology)

Integrating hygienic Entities: *hidden* Information

Text-based Instructions

Ambiguity e.g. missing or bad punctuation, wrong words

"Smokescreens" complex, verbose text

"Misdirection" (bias: design-solutions vs performance-needs)

Product-data Management (PDM) Software

- Used by e.g. Airbus, Boeing, Rolls-Royce, GE, BAE Systems
- Global: multidisciplinary inputs and feedback
- "Virtual" or "digital" twin
- Real-time dossier and history
- Underlying reasons and evidence
- Modelling
- Communication (e.g. outside the project-team)
- Building-information Management (BIM) software