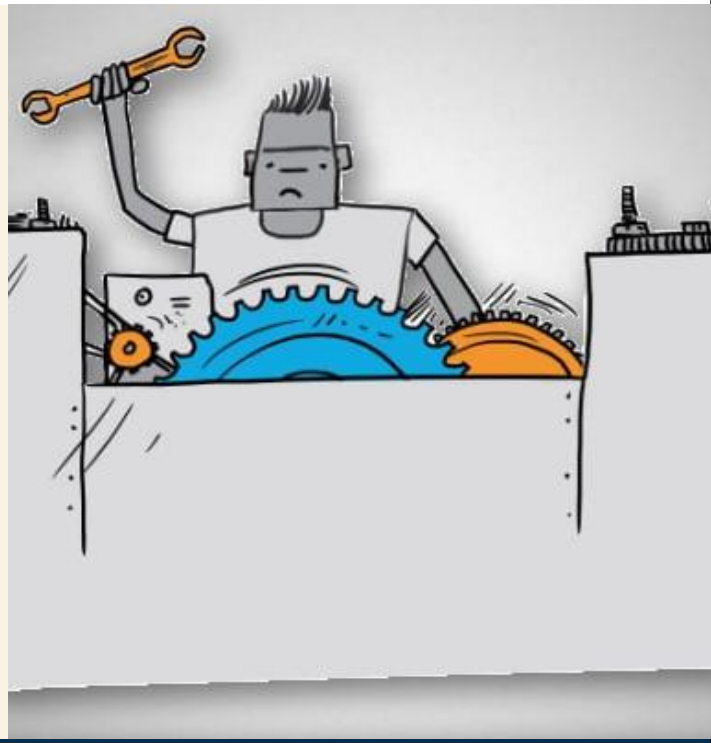
PRODUCT REGULATIONS (CE)
IN RELATION TO
PROCESS INSTALLATIONS

Requirements and practical choices



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FOREWORD

- We are no manufacturers or suppliers
- We are no Notified Body
- We support clients with dealing with their responsibilities from “product” legislation in CAPEX projects
- Quite a lot of confusion about requirements

<u>Purpose:</u>

- Share the most important discussion topics
- Share some learnings from recent practices, with new Machine Regulation
- Possible approach

CONTENT

- Recent changes in regulations
- Discussion topics
- CE conformity process
- Responsibilities
- Our approach: CE plan - step approach - CE file
- Examples
- Conclusions

EU MACHINERY REGULATORY FRAMEWORK

- Until 19 January 2027: Machinery Directive 2006/42/EC applies (MD)
- From 20 January 2027: EU Machinery Regulation (EU) 2023/1230 is mandatory (MR)
- **New in the Machine Regulation (MR)**: digital manuals, cybersecurity / AI requirements, substantial modifications → possible new CE process.

DISCUSSION POINTS

- Are product regulations also applicable to (process) installations?
- Who is responsible for fulfilling the product requirements (like DoC) for the integrated installation?
- When can a part of the installation be handled as a separate assembly?
- Does integrator take-over responsibility for equipment from suppliers?

IMPORTANT DEFINITIONS MR

- **Machinery:** an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application.

- **Assembly of machinery:** Assemblies of machinery which, in order to achieve the same result, are arranged and controlled so that they *function as an integral whole*

- **Manufacturer**: Manufacturer of products within the scope of the regulation or who has those products designed or manufactured and markets this under its name or trade *or puts those products into service for its own use*.

IMPACT OF CHANGES

- Own use (manufacturer) is defined
- Cyber security/risks of AI must be considered
- Safety functions of process control systems are crucial for demarcation

Result:

- Owner/user is often responsible for CE conformity process for integrated installation
- Process and responsibilities to be defined in CE plan and contracts
- Choices to be made on demarcation of assemblies
- Procurement choices influence demarcation

CE-PROCESS (MR)

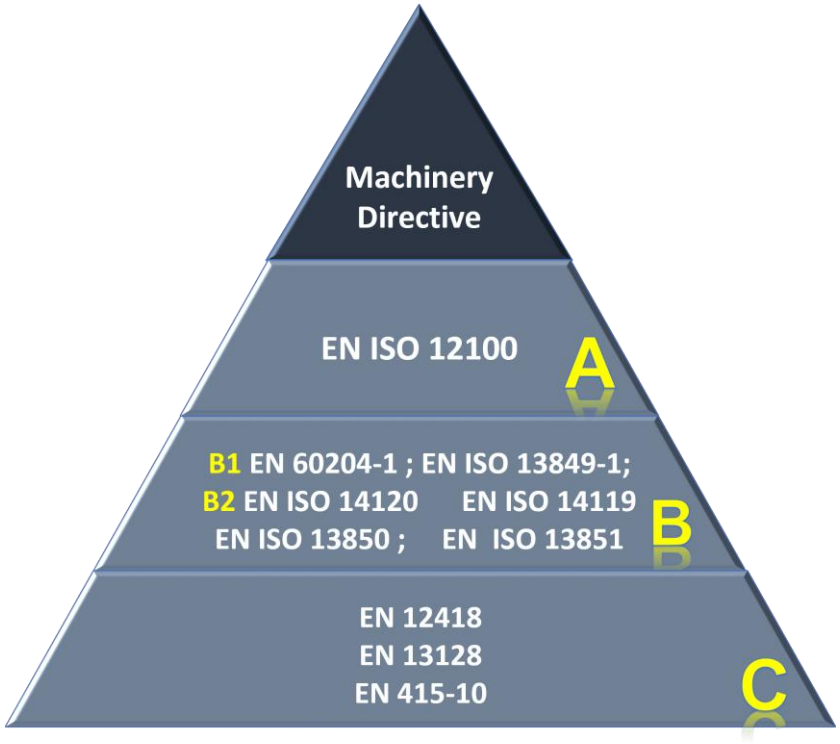
Requirements for manufacturers:

1. Fulfil essential H&S requirements
2. Perform risk assessment (EN ISO 12100)
3. Functional safety process control
4. Compile technical file
5. EU declaration of Conformity
6. CE marking

Above is called conformity assessment

Classification of assessment categories (Annex I)
→ Notified Bodies

Also, for modifications / changes.

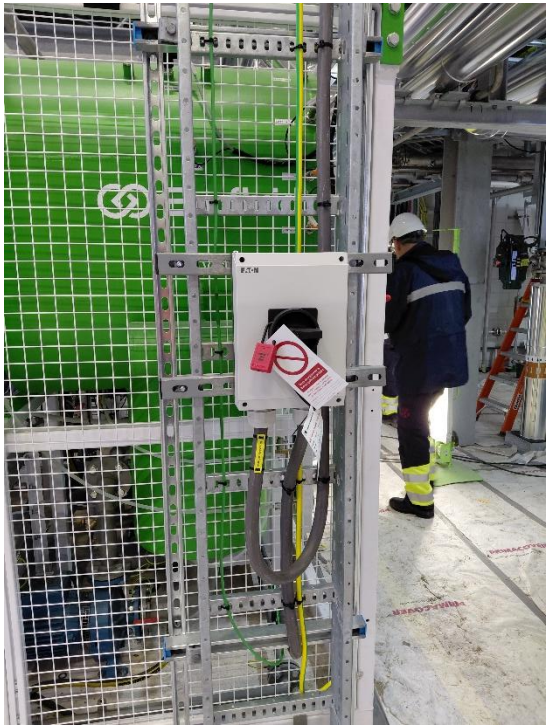


PRACTICE OF PROCESS INSTALLATIONS

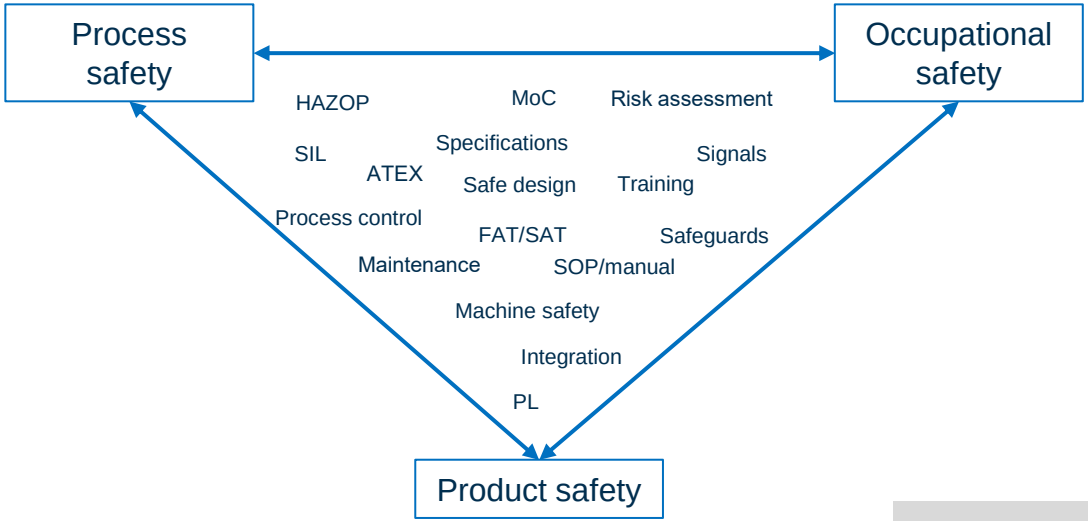
- **Combination of components and parties:**
  - Completed machines (former IIA) - supplier
  - Not-completed machines (former IIB) - supplier
  - Piping and Installations – contractors
  - Cabling and cabinets- contractors
  - Process control (SCADA) – Integrator
  - Turn-key installations - Supplier

Total assemblies will have to comply to

Dutch and European legislation!



SAFETY DOMAINS INVOLVED



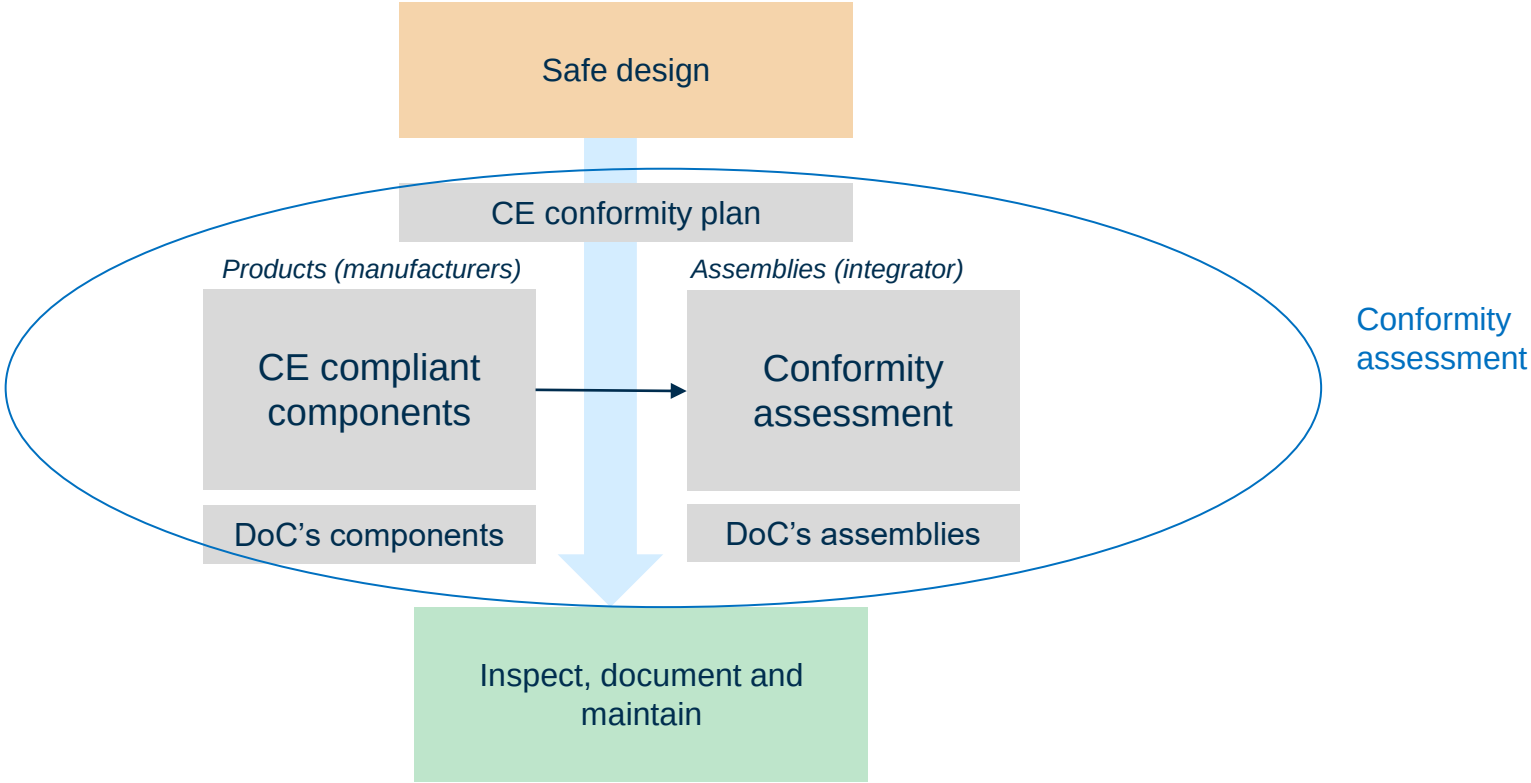
Integrated approach

No domain is more important.

ASSEMBLIES – ROLE OF INTEGRATOR

- CE plan
- Procure compliant components
- Define the conformation route (self or NoBo)
- Define systems/processes (assemblies)
- Perform a system-level risk assessment
- Document & declare (Technical file, CE marking and DoC)
- Manage updates/changes

CE CONFORMITY APPROACH

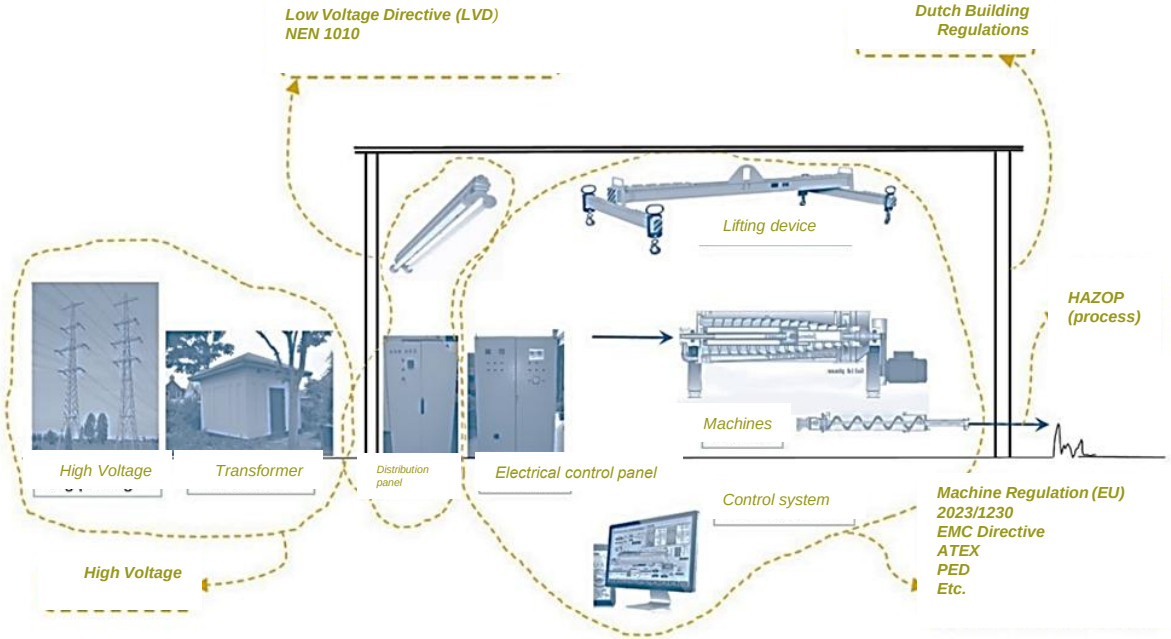


CE RESPONSIBILITY IN CONTROLSYSTEM INTEGRATION

- Different directives and standards
- Dependencies in control systems
- Central or local control of safety functions

- Remember: “can function as a Whole”

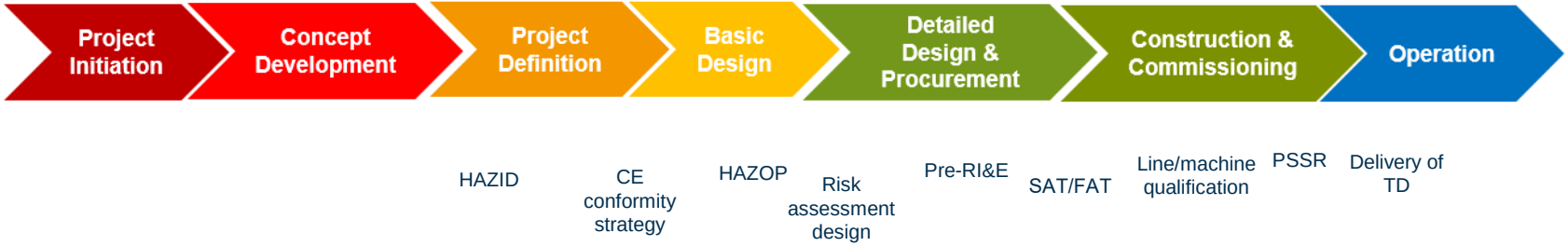
- Manufacturer or integrator can choose demarcation of assemblies based on above (use PFD’s)



OUR APPROACH

INTEGRATION CE CONFORMITY IN PROJECT

- Safe installations/assemblies for operations and maintenance
- CE plan/strategy and CE file (instead of separate documents)
- For the overall process installation manage the risks by performing an HAZID/HAZOP/RI&E
- Example of integrated approach:



CE FILE FORMAT

TAB	Check
Phase 1 – Start, Context & Scope Definition	☐
Phase 2 – System Definition & Technical Design	☐
Phase 3 – Cybersecurity & Digital Aspects (if applicable)	☐
Phase 4 – Core Risk Identification & Evaluation (Machinery / System Level)	☐
Phase 5 – Process and Functional Safety	☐
Phase 6 – Directive-Specific Risk Identifications & Evaluations	☐
Phase 7 – Results, Residual Risks & Follow-up	☐
Phase 8 – PSSR (Pre-Start-up Safety Review)	☐
Phase 9 – Formal CE Closure	☐

RISK ASSESSMENT

- Combination of Essential Safety requirements and NEN-EN-ISO 12100
- Performed in three stages
  - Design review (3D models)
  - FAT/SAT
  - PSSR Measures, risk calculation, control of residual risks

1. Machinery Checklist and risk assessment					
Nr	Checkpoint	How to Check	Design Review	SAT (mechanical complete)	PSSR
	1,1 Documentation	Align titles with essential safety requirements from Directives			
1.1.1	Is a list of directives, standards and legal requirements used for the machinery safety provided including a declaration of Conformity (if required)?	Obtain and review the document provided by the supplier.	NA	3	3
1.1.2	Has the supplier provided a document detailing the hazards associated with the equipment, an assessment of the associated risks, and details of the methods used to eliminate or reduce those risks?	Obtain and discuss the document with the supplier to ensure all hazards have been identified, eliminated or reduced as much as possible.	NA	2	3

EXAMPLES

EXAMPLE I

- Sector: Chemical
- Machine Directive focussed, PED added later
- Approach and file format was developed along the project
- Much time spend on reviewing suppliers' documentation
- Learning: Involve NoBo (PED) during design
- Different DoC’s for MD and PED, because of classification of PED categories, not budgeted

EXAMPLE II: WWTP

- New process in wastewater plant
- Existing CE plan not specific, lot of references to legislation
- Responsibilities for involved parties not clear - who is going to do what?
- Skids to be considered as independent installations or not?

EXAMPLE III: NUCLEAR FACILITY

- MR to be used
- Nuclear exclusion, only if contradictions occur
- Non-European design company
- Unfamiliar with Directives, training/support needed
- Example: Door and hatch closing - Control narratives

CONCLUSIONS AND ANSWERS

CONCLUSIONS

- Safety domains need the same basics
- CE conformity assessment can be integrated in the (process) safety processes
- Does not require much more activities than a Best Practice approach
- The CE file just summarizes and shows evidence of compliance

DISCUSSION POINTS

- Are product regulations also applicable to (process) installations?

Often YES

- Who is responsible for fulfilling the MR requirements (DoC) for the integrated installation?

Manufacturer/ user

- When can a part of the installation be handled as a separate assembly?

"As a whole"

- Does integrator take-over responsibility for equipme suppliers?

No, just integration

QUESTIONS

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