Machine Safety and related workflows and interfaces

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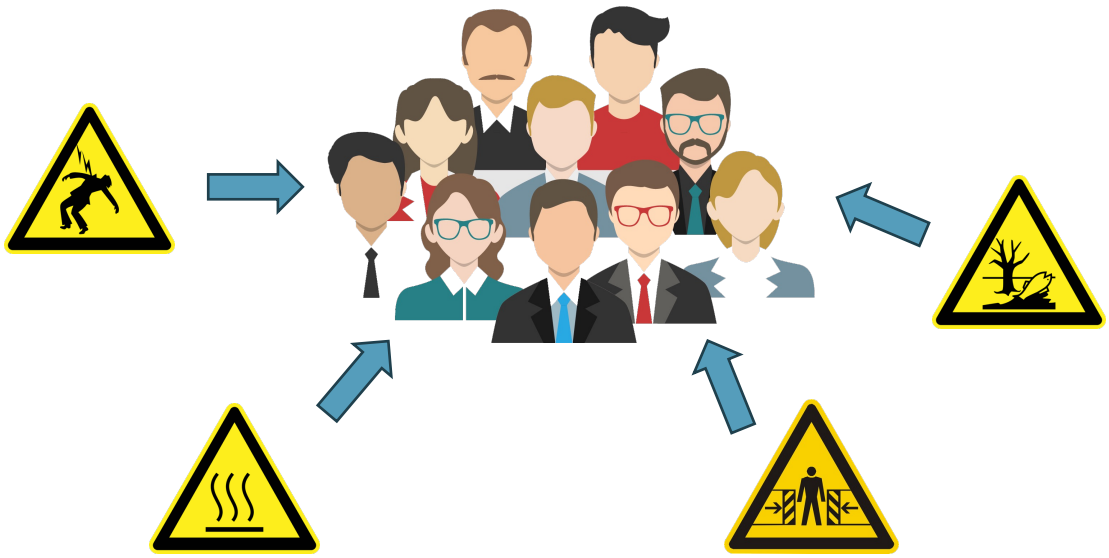
Dr. Patrick Geßler
Electronic and Electrical Engineering
Group Leader
patrick.gessler@xfel.eu

Agenda and disclaimer

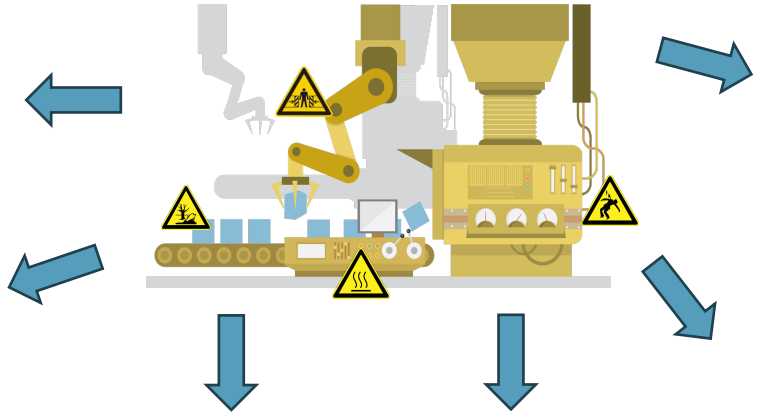
- Legal and practical background
- How we want to develop procedures and expertise in our institute
- Some of the findings so far
- Topics with interest for discussions
- Outlook

Disclaimer: Information collected and presented in theses slides are to the best of my knowledge and understanding. But I can not guaranty correctness and completeness. Only the original directives, regulations, laws, etc. are binding.

Two parallel approaches to ensure safety for people – required by law



Ensure safety for employees at their tasks and work place



Design and build only safe “machines”

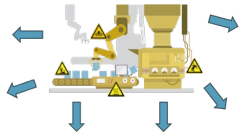
Two parallel approaches to ensure safety for people – required by law

Ensure safety for employees at their tasks and work place

Richtlinie 89/391/EWG
Durchführung von Maßnahmen zur Verbesserung der Sicherheit und des Gesundheitsschutzes der Arbeitnehmer bei der Arbeit

92/58/EWG
Mindestvorschriften für die Sicherheits- und/ oder Gesundheitsschutzkennzeichnung am Arbeitsplatz
2009/104/EG
Mindestvorschriften für Sicherheit und Gesundheitsschutz bei Benutzung von Arbeitsmitteln durch Arbeitnehmer bei der Arbeit
…

- Arbeitsschutzgesetz (ArbSchG)
- Betriebssicherheitsverordnung (BetrSichV)
- Verordnung über Arbeitsstätten (ArbStättV)



Design and build only safe “machines”

Richtlinie 2006/42/EG
“Maschinenrichtlinie / Machine Directive”
Maschinen und zur Änderung der Richtlinie 95/16/EG

CE conformity concept

2014/30/EU - EMV Richtlinie
2014/35/EU - Niederspannungsrichtlinie
2001/95/EG - Produktsicherheitsrichtlinie
…

- Produktsicherheitsgesetz (ProdSG)
- Verordnung über elektrische Betriebsmittel (1. ProdSV)
- Elektromagnetische-Verträglichkeit-Gesetz (EMVG)
- …

Two parallel approaches to ensure safety for people – required by law

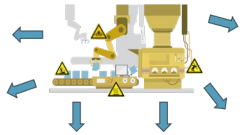
Ensure safety for employees at their tasks and work place

Some further stakeholders and information sources:

DGUV
Deutsche Gesetzliche Unfallversicherung
Spitzenverband

baua:
Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

Technische Regeln für Betriebssicherheit (TRBS)
Empfehlungen zur Betriebssicherheit (EmpfBS)
Bekanntmachung zur Betriebssicherheit (BekBS)



Design and build only safe “machines”

Some further stakeholders and information sources:

- Various norms
- “state-of-the-art”

IFA
Institut für Arbeitsschutz der
Deutschen Gesetzlichen Unfallversicherung

- Leitlinien
- Handbücher
- “Kochbücher”
- Software

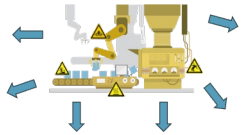
Two parallel approaches to ensure safety for people – required by law

Ensure safety for employees at their tasks and work place

What does it (at least) mean for us?

- Select, buy and operate only safe equipment machines
  - → in-line with the law
- Carry out and regularly repeat risk assessments (Gefährdungsbeurteilungen) for
  - → Tasks carried out by employees
  - → Equipment / machines which are used / operated

  Required BEFORE installing / operating
- Electrical safety checks
  - → Required BEFORE installing / operating
  - → Repeated regularly (frequency depends on risks)
- Regular safety instructions to employees
- Everything needs to be documented



Design and build only safe “machines”

What does it (at least) mean for us?

- If we significantly change (bought) machines, we become the manufacturer
  - → Requires to fulfill all the previous obligations
- If we buy a “partial” machine, we do the rest of the design and building process and thus become the manufacturer
  - → Requires to fulfill all the previous obligations
  - → Original manufacturer provides documentation
- If we buy a non-conform machine, we need to take over the manufacturers obligations
  - → When procuring outside EU, to be done before importing
- For machines we design and build (alone or with external support, we are the manufacturers
  - → Thus we have to fulfil the previously described obligations

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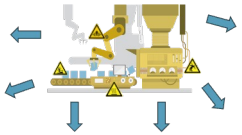


Design and build only safe "machines"

Ambiguous statement in Machine Directive, similarly also in related directives and derived laws:

Maschinenrichtlinie

(2) Vom Anwendungsbereich dieser Richtlinie sind ausgenommen:

h) Maschinen, die speziell für Forschungszwecke konstruiert und gebaut wurden und zur vorübergehenden Verwendung in Laboratorien bestimmt sind;

EMV Gesetz

(3) Auf folgende Betriebsmittel finden nur die §§ 27 bis 30 dieses Gesetzes entsprechende Anwendung:

3. kunden- und anwendungsspezifisch angefertigte Erprobungsmodule, die von Fachleuten ausschließlich in Forschungs- und Entwicklungseinrichtungen für Forschungs- und Entwicklungszwecke verwendet werden,

An interpretation is described in the DGUV Information 202-002

→ We still have to follow the directives / laws in designing safe machines

Two parallel approaches to ensure safety for people – required by law

Residual risks for employees declared in the users manual of the machine have to be included in the “Gefährdungsbeurteilung” and measures taken where required

In parallel to the design and manufacturing, risks have to be identified in the “Risikoanalyse” and reduced in order to build an inherently safe machine. Residual risks over the whole life cycle of the of the machine have to be documented in the users manual

Typical use cases how new machines come to our institute

Buy it

Procurement of a commercial of the shelf (COTS) product **with** CE conformity which is used as-is

Procurement of a COTS product **without** CE conformity (e.g. outside of EU)

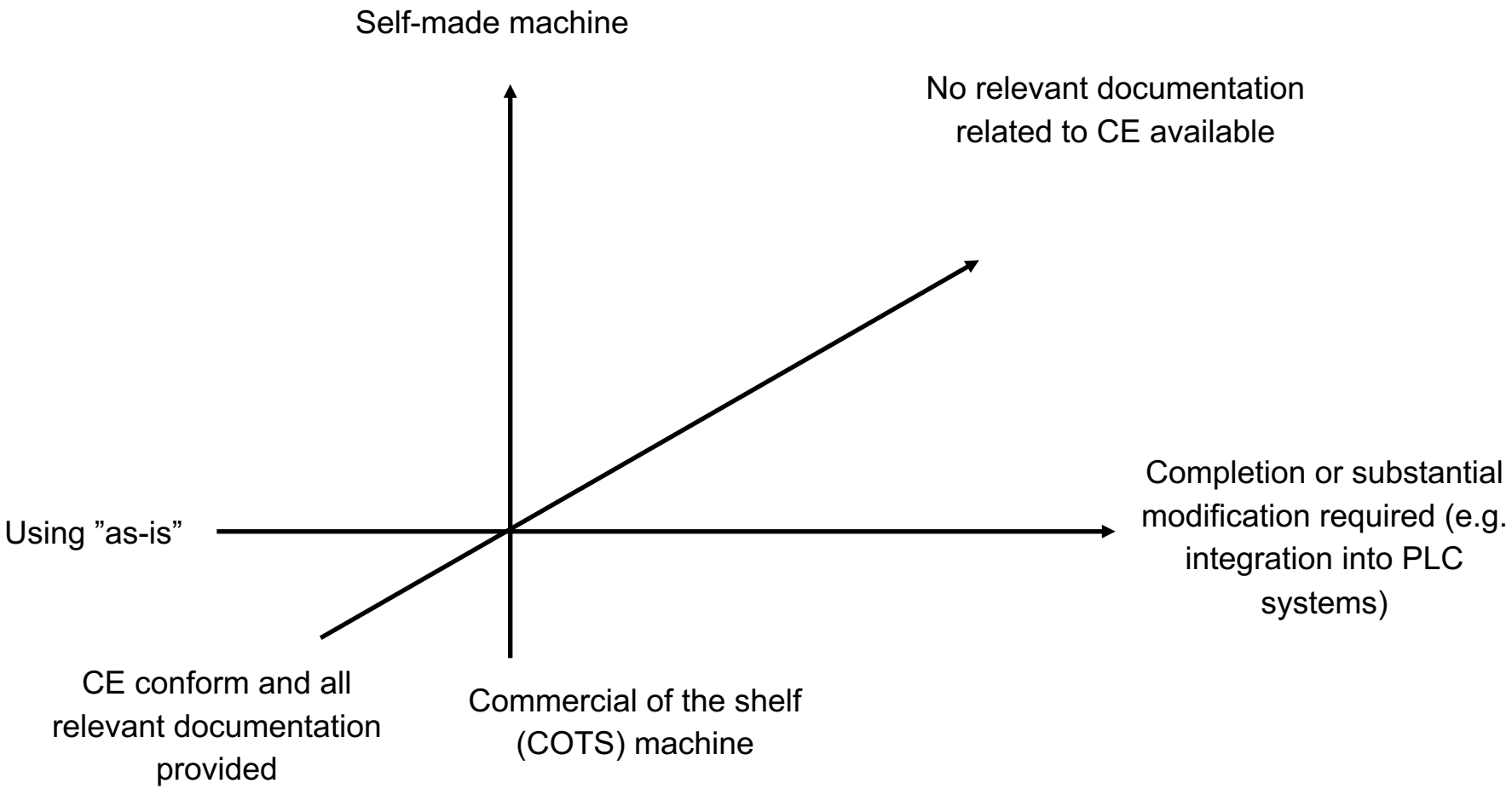
Build it

Procurement of a commercial of the shelf (COTS) product **with** CE conformity which **needs** tight **integration** into beamline and electronic

Own design and also in-house build and integrated

Tendering of a special system (machine or partial machine) based on requirements by our institute (with or without CE related documentation)

”Dimensions” of the use cases



The process to our CE process – Project: ProMAP

- The level of knowledge of legal requirements, norms and procedures was low
  - Across our institute, but also for many supplying companies or institutes
- Many aspects of the CE related process where counter intuitive for many colleagues
  - That made it even harder for the other to get the support
- An internal development project had been initiated - ProMAP
  - **Pro**cesses required for **M**anufacturing, **A**ssembling and **P**rocuring
  - Interdisciplinary team (legal, procurement, engineering, science, project office, external experts,…)
  - Better identify the use cases and the ways to deal with them across the institute
  - Develop processes
  - Gain and spread the required knowledge, organize trainings
  - Establish required tools, standard solutions database
  - Develop structure and roles of experts in the institute

ProMAP – Some important findings so far

- Changes of standard procurement documents (AGB, tendering documents, etc.)
  - Including required or even very helpful documentation like the risk assessments
  - Including mitigation strategies for cases when the company is not able to conform with legal requirements – we have to support or take over some of the duties
- Special software for machine safety risk assessment and safety concept
  - We decided to use Safexpert for that purpose
  - Developing standardized approaches and “data base” like selectable risks and reduction measures
- Establishing expert role in machine safety in scientific and instrumentation groups
- Documentation of workflows
- *Knowledge exchange with other institutes*, companies and external experts

Topics triggering vivid discussions – would be nice to get your view as well

- Where do boundaries of machines end (e.g. one small entity up to the whole facility)
- What kind of risks are regarded as safe to operate and do not need a specific machine safety implementation (e.g. standardize residual risks) – rather covered in “Gefährdungsbeurteilung”
- Special machines we build on our own:
  - how to we get good state of the art information to comparable ones
  - E.g. mapping to Norms of comparable machines – requires a lot of knowledge / experience
- Buying and using complete machines as black-box vs. self integration and creating substantial change

Outlook

- Establishing an efficient machine safety procedure and the required knowledge and tools is hard
  - We are still in the process to do that and will need further time to achieve it – hopefully this year
  - Building up the underlying data bases and make the process efficient will take longer

- There are further aspects to be looked at
  - In 2026/2027 the new Machine Regulation 2023/1230 will come into practice
    - ► Fully from 14. Januar 2027 onwards
    - ► Some aspects already mid 2023 (lifting machines related) and beginning 2024
  - This also includes more aspects related to cyber security, AI, remote access, etc., which is not only a topic of machine safety