

Quality Assurance

Training Module: Directives, Laws and Standards
(to ease your life)



A vertical diagram on the left side of the slide, consisting of five circles connected by a blue line. The top circle is solid blue, while the four circles below it are white with blue outlines. Each circle is connected to a horizontal blue bar that contains the text for that agenda item.

Introduction

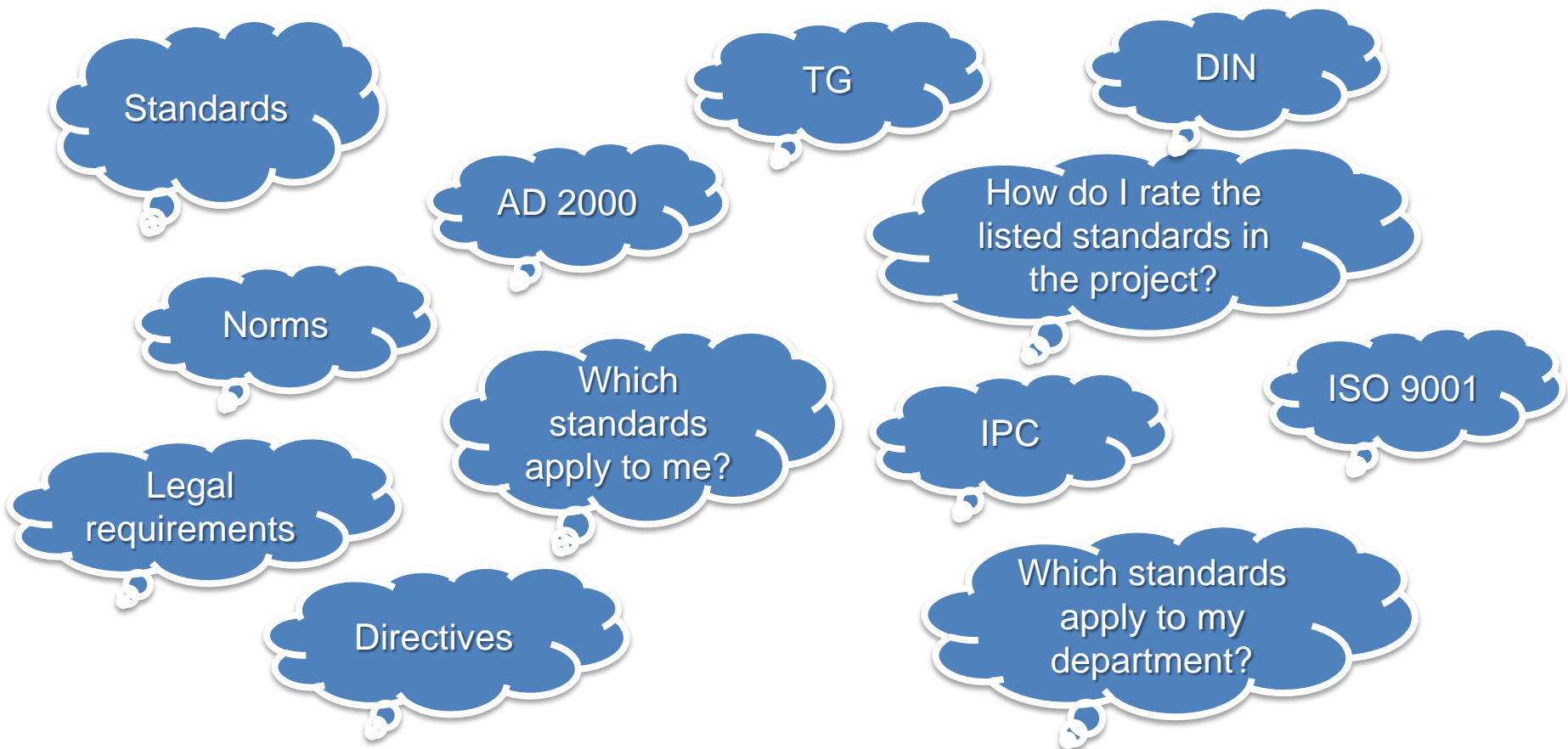
Documents

Processes & Methods

Experiences & Tips

Summary

- There are a lot of standards and questions about their applications and obligations in the project



- To clarify the following questions:
 - What different standards are there?
 - Which standards do we have to adhere to?
 - What benefit do we have in the project?
 - How do we document this in the project?
 - What tools are available to us to define the correct standards?



Definitions

Term	Description
Directive (<i>Richtlinie</i>)	An directive in the context of the European Union is a framework law obliging the member states to achieve a specific objective
Law (<i>Gesetz</i>)	Collection of generally binding legal rules
Ordinance (<i>Verordnung</i>)	Details the law and should make it applicable
Regulation (<i>Vorschrift</i>)	Legal act that becomes immediately enforceable as law
Guideline (<i>Leitfaden</i>)	Tool for the implementation of legal or regulatory requirements
Norm (<i>Norm</i>)	Technical regulation in general

Must be taken into account

This helps to fulfil the legal obligations and ensures the state of the art aspect.

➤ In the following the term “**standard**” is used as collective term



Examples

Term	Example
Directive (<i>Richtlinie</i>)	<ul style="list-style-type: none">• Machinery Directive (2006/42/EC)• Low Voltage Directive (2014/35/EU)• Pressure Equipment Directive (2014/68/EU)
Law (<i>Gesetz</i>)	<ul style="list-style-type: none">• German Civil Code (BGB)• German Road Traffic Act (StVG)
Ordinance (<i>Verordnung</i>)	<ul style="list-style-type: none">• 1st Ordinance concerning the ProdSG Ordinance on the placing on the market of electrical equipment within certain voltage limits• 6th Ordinance concerning the ProdSG Ordinance on the placing on the market of simple pressure vessels
Regulation (<i>Vorschrift</i>)	<ul style="list-style-type: none">• Accident prevention prescription issued by the German employers liability insurance associations with legal character, e.g.<ul style="list-style-type: none">• DGUV Regulation „Principles accident prevention regulation“
Guideline (<i>Leitfaden</i>)	<ul style="list-style-type: none">• Guideline of the German Statutory Accident Insurance Association (DGUV): BGI/GUV-I 5139 -> DGUV 202-002
Norm (<i>Norm</i>)	<ul style="list-style-type: none">• VDE, DIN, EN, ISO, IEC, etc.



Transfer of EU directives into German law

- The guideline DGUV 202-002 (old: BGI/GUV-I 5139E) describes the transfer of EU law into German law (→ it is part of our General Specification)



EU directives	Transposition into German law	Additional ordinance
Low Voltage Directive 2014/35/EU	Product Safety Act (ProdSG)	Ordinance on the market of electrical equipment within certain voltage ranges (1 st Ordinance concerning the ProdSG)
Directive on simple pressure vessels 2014/29/EU		Ordinance on the market of simple pressure vessels (6 th Ordinance concerning the ProdSG)
Machinery Directive 2006/42/EC	Act on Occupational Safety and Health (ArbSchG)	Machinery Ordinance (9 th Ordinance concerning the ProdSG)
ATEX Directive 2014/34/EU (ATEX)		Explosion Protection Ordinance (11 th Ordinance concerning the ProdSG)
Pressure Equipment Directive 2014/34/EU	Electromagnetic Compatibility Act	Pressure Equipment Ordinance (14 th Ordinance concerning the ProdSG)
Directives on the health and safety of workers 89/391/EEC 95/63/EG 2001/45/EC		Ordinance on Industrial Safety and Health (BetrSichV)
EMC Directive 2014/30/EU		

...an ordinance is to be seen as a law and cannot be excluded without justification!

“Betriebssicherheitsverordnung” (BetrSichV) describes the use of work equipment.

Low Voltage Directive → Product Safety Act → Ordinance



Directives with legal obligation



DGUV Regulations	
DGUV Regulation 1	Principles accident prevention regulation
DGUV Regulation 2	Occupational physicians and Occupational Safety and Health professionals
DGUV Regulation 3	Electrical installations and equipment
...	...

We (as employer) must take it into account from the perspective of accident insurance.

Work contract or In-Kind contract	
Contract	The actual contract only
General-, Common-, Detailed Specification, Technical Guideline	Applicable documents
Norms, Guidelines	Applicable DIN EN ISO IEC

We (as a contract partner) must take it into account.



What does “State of the art” mean?



Some examples for „State of the art“

TRBS	<p>Technical Rules for Industrial Safety / Technische Regeln für Betriebssicherheit</p> <p>1000er Generally valid technical rules for operational safety</p> <p>1111 Risk assessment and safety evaluation</p> <p>1201 Testing of operating means and plant requiring monitoring</p> <p>1203 Qualified persons - Special requirements - Electrical hazards</p> <p>2000er Hazard-related rules / Gefährdungsbezogene Regeln</p> <p>...</p>
DGUV (BGI)	<p>Regeln, -Information, -Grundsätze</p> <p>BGI / DGUV-I 5139 Manufacturing and operation of equipment designed for research purposes</p> <p>BGV_B11 Notification of the recast Ordinance on Electromagnetic Fields</p>
IPC	Institute for Printed Circuits
VDE	Verband der ET, ... (German Testing and Certification Institute)
IEC	International Electrotechnical Commission
EN	European Norm
ISO	International Organization for Standardization
	...

We must take it into account after closing a contract.

If we stick to it, we fulfil the presumption of conformity for approach of designing, building and testing everything according to the state of the art.

What are the advantages of using standards in our project?



- ✓ The fact that **standards are unambiguous, generally accepted rules** of technology lends contracts that refer to standards greater legal certainty
- ✓ Standards **increase safety**
- ✓ Standards provide **clarity and transparency for suppliers and their customers**, and facilitate the design, production and maintenance processes
- ✓ Standards help to make **production processes more efficient** and ensure a more consistent, comparable quality of products, thus enhancing consumer trust
- ✓ Standards ensure **product and services are state of the art**
- ✓ **Standards lead to** easier documentation

Source: www.din.de



“The design must comply with...”

Some examples:

- **Electricians**
DIN EN 60204-1 Safety of machinery - Electrical equipment of machines - Part 1
DIN EN 60204-11 Safety of machinery - Electrical equipment of machines - Part 11: **Requirements for HV equipment** for voltages above 1000 V a.c. or 1500 V d.c
- **Electronics**
IPC-A-610 Description of **production quality** of PCBs
- **Cables**
DIN EN 61442:2006-01; VDE 0278-442:2006-01 Test methods for accessories for power cables with rated voltages from 6 kV up to 36 kV ($U_m = 42$ kV)

A simple sentence describes the test requirements or tolerances



“The design must comply with...”

Some examples:

- **Mechanics**
ISO 2768-1 /-2 **Standard tolerance** norm
- **Welding**
DIN EN ISO 3834-1 ff -5 Quality requirements for fusion welding of metallic materials / Criteria for selection of the appropriate **quality requirements**
- **Pressure vessels**
AD 2000- set of rules Specifies all **basic safety and conformity requirements** that must be observed in accordance with the European Pressure Equipment Directive 2014/68 / EU (PED)
- **Vacuum**
DIN 28429:2014-05 Vacuum technology - **Acceptance specifications** for ion getter pumps

A simple sentence describes the test requirements or tolerances



Where standards are located at GSI



- VDE, EN, ISO, IEC standards
Department GAT, EPS and ETE
- Safexpert (if appropriate standard package is purchased)
Department ENG / TIN
- \\campus\Normen\Normen-Standards
QMO

➤ Some standards are linked on the intranet page of the QUA:
www.gsi.de/qua





Preparations

- Define the main legal standards with the specification phase

Doing

- Legal standards are defined by the contract
- Define additional standards elaborated in the safety related risk assessment
- Evaluate the test plan and test results during the FAT & SAT

Storing

- All Documentation is stored in EDMS or comparable DMS (using the template "Required Documents")



- With conclusion of the contract, the **elementary standards are fixed**

GS	General Specification
CS	Common Specification
DS	Detailed Specification
TG	Technical Guideline

- By carrying out the **safety related risk assessment**, the safety standards are specified which must be observed

CDR	Conceptual Design Review
FDR	Final Design Review

- The **validation of the application of the standards** takes place with the test record

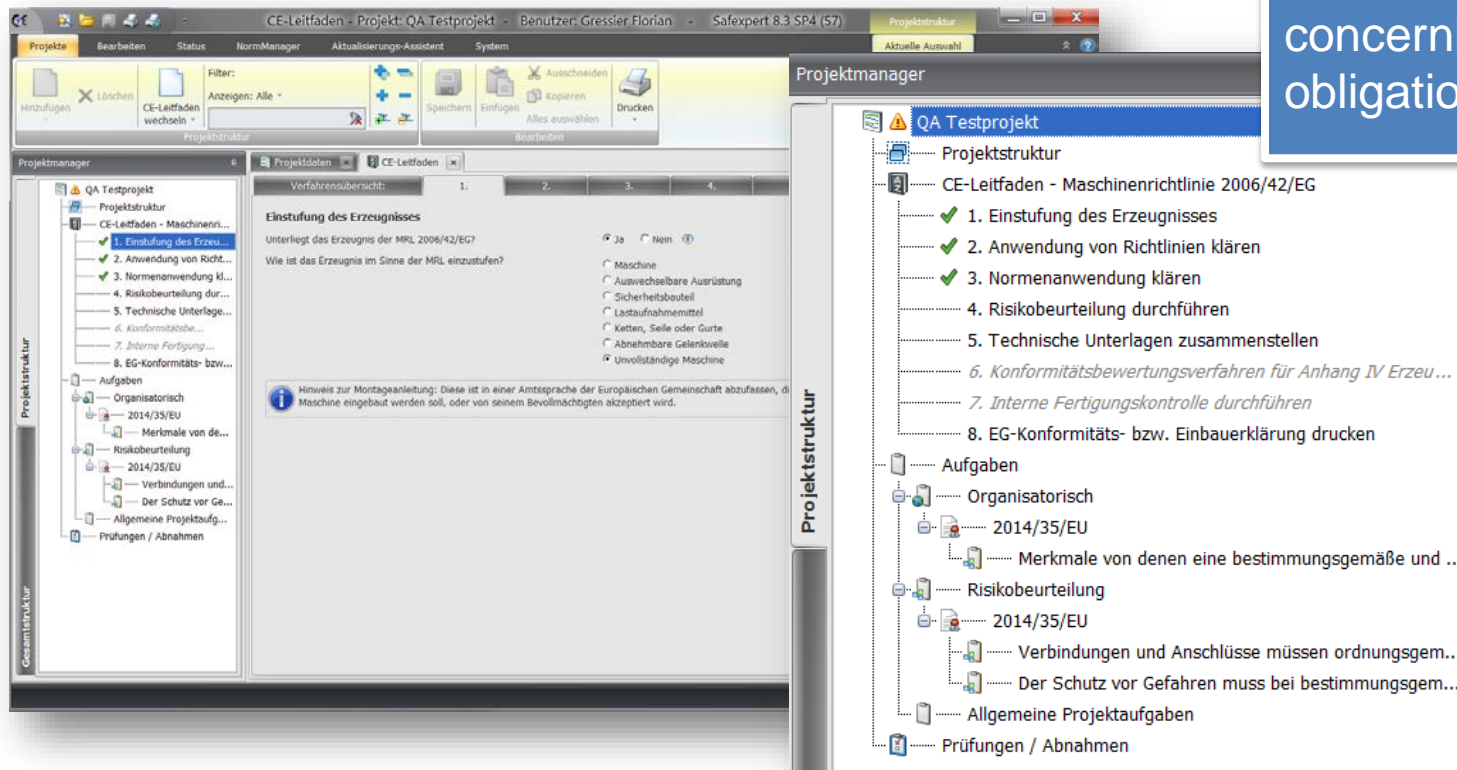
FAT	Factory Acceptance Test
SAT	Site Acceptance Test

Contribution to ensure that the FAIR GSI GmbH installation complies with the applicable laws and regulations, including the associated proof of conformity.



- What tools are available to us, to define the correct legal requirements?
 - Software: “Safexpert“ is established by GSI / **ENG**

With this tool we can generate a list of required documents concerning legal obligations.



The screenshot displays the Safexpert software interface. The main window is titled 'CE-Leitfaden - Projekt: QA Testprojekt'. The interface is divided into several panes:

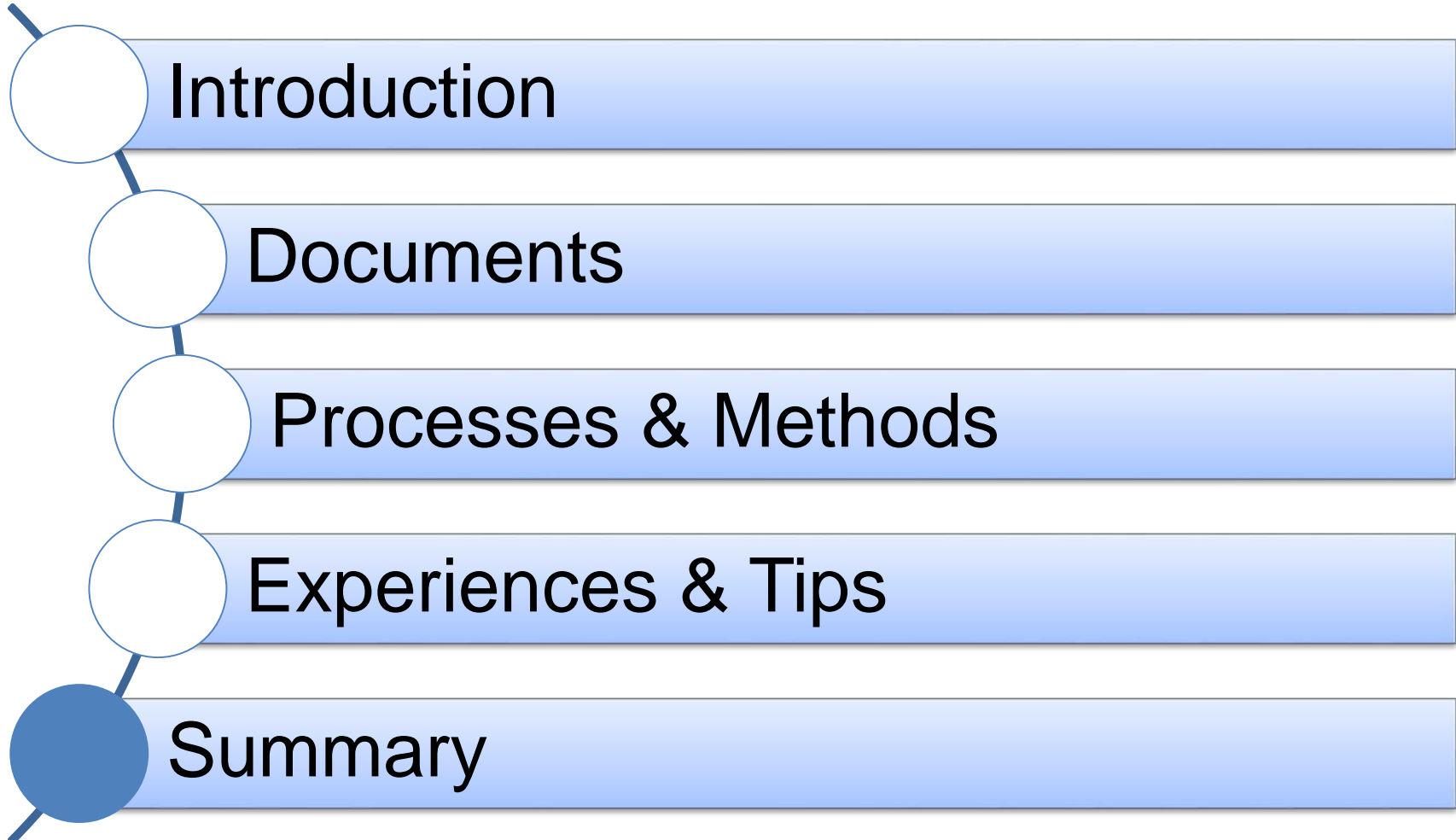
- Project Manager (Projektmanager):** Shows a tree view of the project structure, including 'QA Testprojekt', 'Projektstruktur', 'CE-Leitfaden - Maschinenrichtlinie 2006/42/EG', and 'Aufgaben'.
- Task List (Aufgaben):** A list of tasks with checkboxes, including '1. Einstufung des Erzeugnisses', '2. Anwendung von Richtlinien klären', '3. Normenanwendung klären', '4. Risikobeurteilung durchführen', '5. Technische Unterlagen zusammenstellen', '6. Konformitätsbewertungsverfahren für Anhang IV Erzeugnisse durchführen', '7. Interne Fertigungskontrolle durchführen', and '8. EG-Konformitäts- bzw. Einbauerklärung drucken'.
- Task List (Aufgaben):** A list of tasks with checkboxes, including 'Organisatorisch', '2014/35/EU', 'Merkmale von denen eine bestimmungsgemäße und ...', 'Risikobeurteilung', '2014/35/EU', 'Verbindungen und Anschlüsse müssen ordnungsgemäß sein', 'Der Schutz vor Gefahren muss bei bestimmungsgemäßer Verwendung sichergestellt sein', and 'Allgemeine Projektaufgaben'.
- Task List (Prüfungen / Abnahmen):** A list of tasks with checkboxes, including 'Prüfungen / Abnahmen'.

Why we must generate a list of department standards?

- In order to set up the plant **safely** and **ensure later operation**, the specialist **departments must know their standards** and must have the **qualified persons** (e.g. electricians) available
- For the **FAT / SAT** acceptance tests, the **standards must be known** and implemented in the **test plans**
- Also in the **reviews** of the test protocols the knowledge of the standards must be present

“Betriebssicherheitsverordnung” (BetrSichV) describes the use of work equipment and regulates the qualification and instruction of the employees.

For “qualified persons” the TRBS 1203 describes more details, e.g. *special requirements for electricians*.



- **What different standards are there?**
Directives → Ordinances → EN, ISO, IEC
→ DGUV Regulations → Guidelines
- **Which standards do we have to adhere to?**
Directives always (justification needed if not!)
→ See contract and risk assessment
- **What benefit do we have in the project ?**
Standardized procedures, a clear identification of the accompanying documentation
- **How do we document this in the project ?**
In separate EDMS container for each system
- **What tools are available to us to define the correct standards?**
Safexpert, experience with ongoing projects, PMO-QUA

Thank you!