

CE conformity & Final Acceptance required documentation

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- General objective
- Fundamentals and framework conditions
 - Directives, standards
 - Partners, roles and responsibilities
 - Structure of the plant
 - Overview of the risk assessment process
- Identification of the occurring hazards
- Realisation process
- Documentation
 - Technical documentation
 - Declaration of conformity / Declaration of incorporation
 - Operation manual
 - Assembly instructions

General objective

- To ensure the safety of people during construction, operation and dismantling of the plant in accordance with the legal requirements and regulations.
- Ensuring legally compliant verification with regard to the conformity of the system

FAIR GmbH must prove conformity with the statutory regulations.

Proof is based as far as possible on the Machinery Directive, as this is most suitable for proof of conformity of our plant after consulting TÜV.

Application of guidelines for:

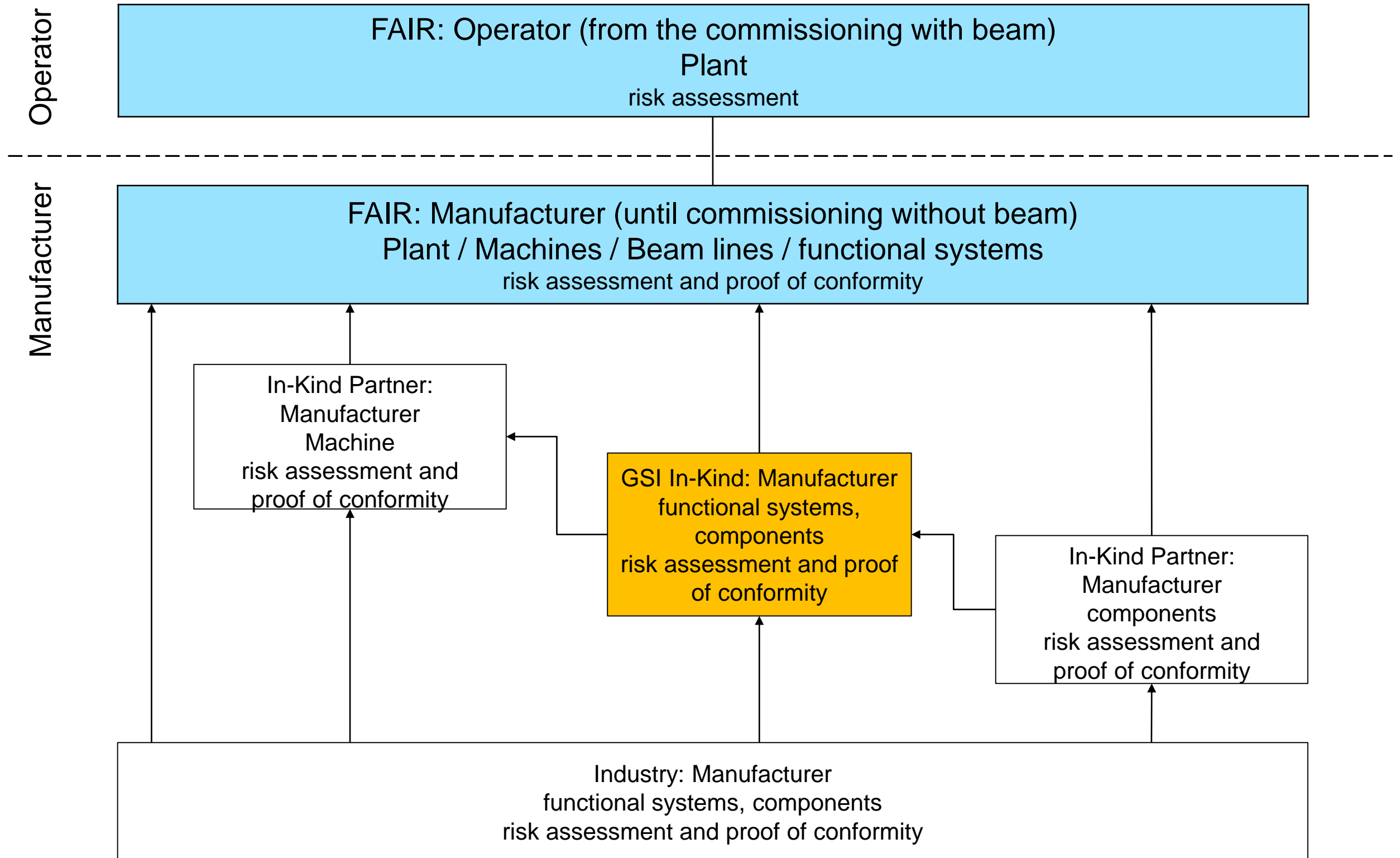
- Plant / Machine / Experiments:
 - Machinery directive
 - Pressure equipment directive
 - EMV-directive
- Functional systems:
 - Machinery Directive or Low Voltage Directive
 - Pressure equipment directive
 - EMV-Directive

Application of standards:

- EN ISO 12100:2010 (D):
 - Risk assessment process
 - Hazard list
- Product-specific standards

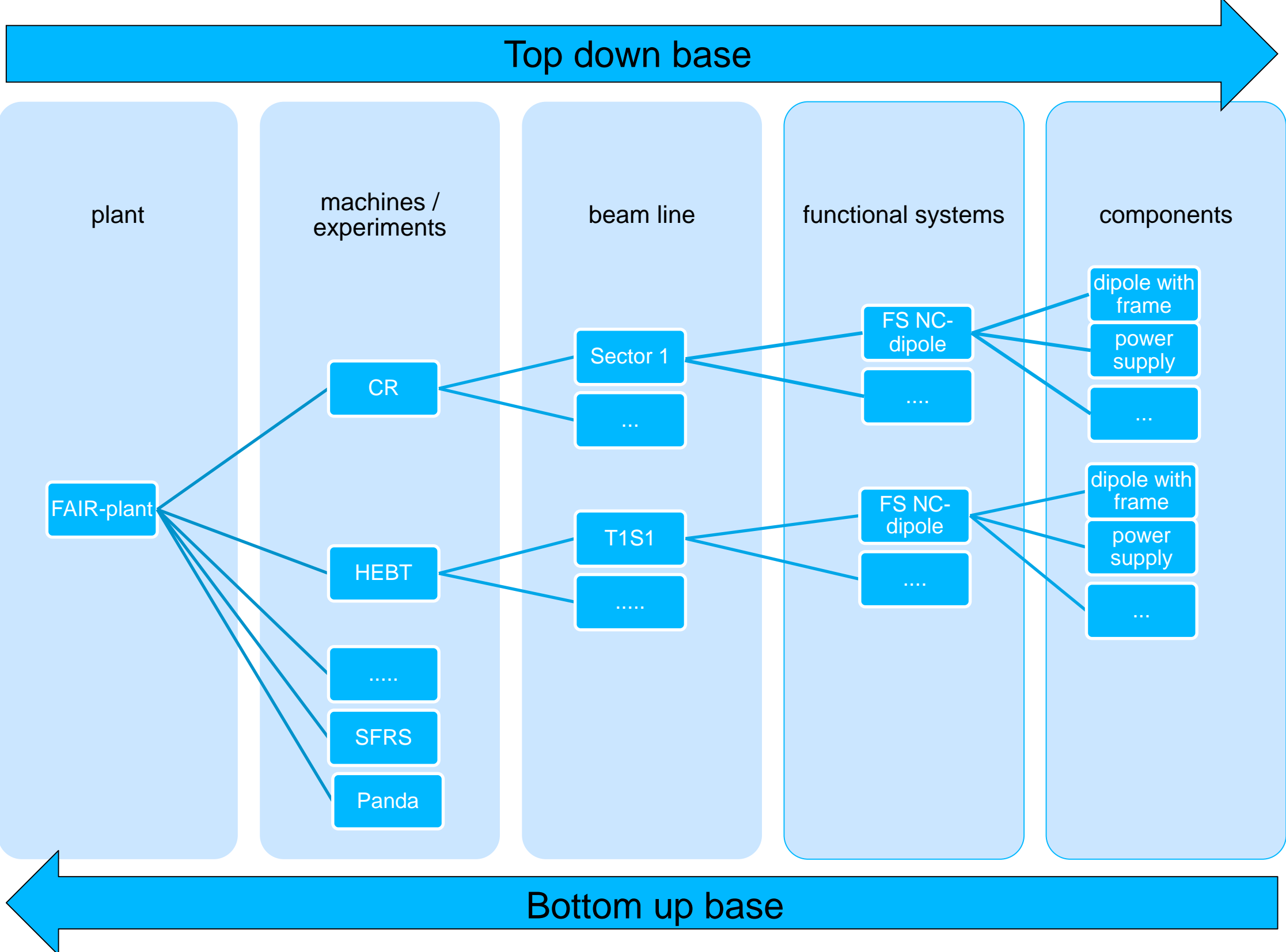
Fundamentals and framework conditions

Partners, roles and responsibilities



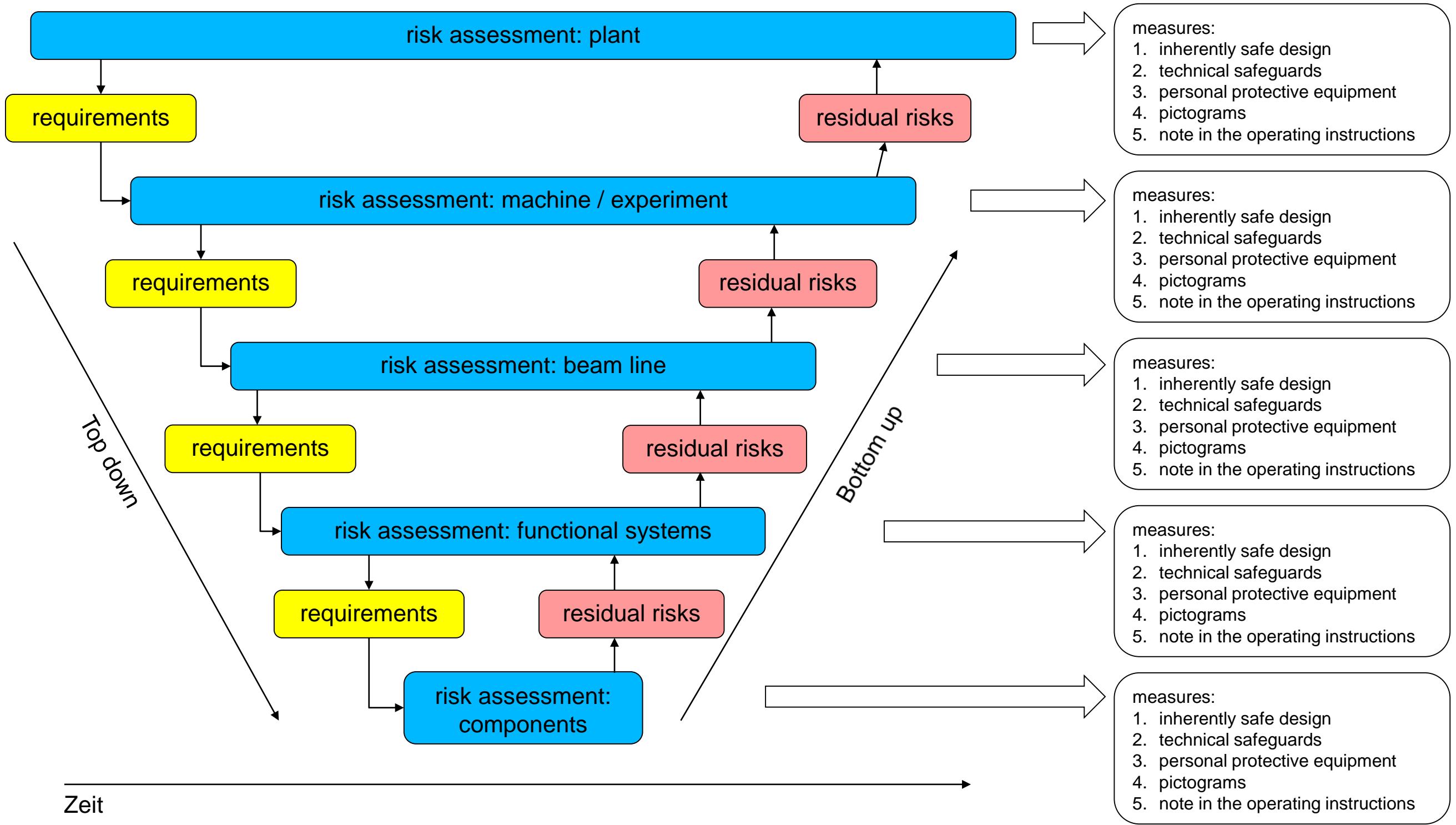
Fundamentals and framework conditions

Structure of the plant



Fundamentals and framework conditions

Overview of the risk assessment process



Identification of the occurring hazards

List of hazards according to EN ISO 12100:2010 (D)

1	Mechanical hazards
2	Electrical hazards
3	Thermal hazards
4	Noise hazards
5	Vibration hazards
6	Radiation hazards
7	Hazards caused by materials and substances
8	Ergonomic hazards
9	Hazards in connection with the operating environment of the machine
10	Combination of hazards

 relevant for FAIR

mechanical hazards

squeezing

impact

clippers

slips, trips, falls

electrical hazards

effects on medical implants

fatal electric shock

fires

(electric) shock

thermal hazards

incineration

frostbite

scalding

radiation hazards

other hazards
damage to body tissue

hazards caused by materials and substances

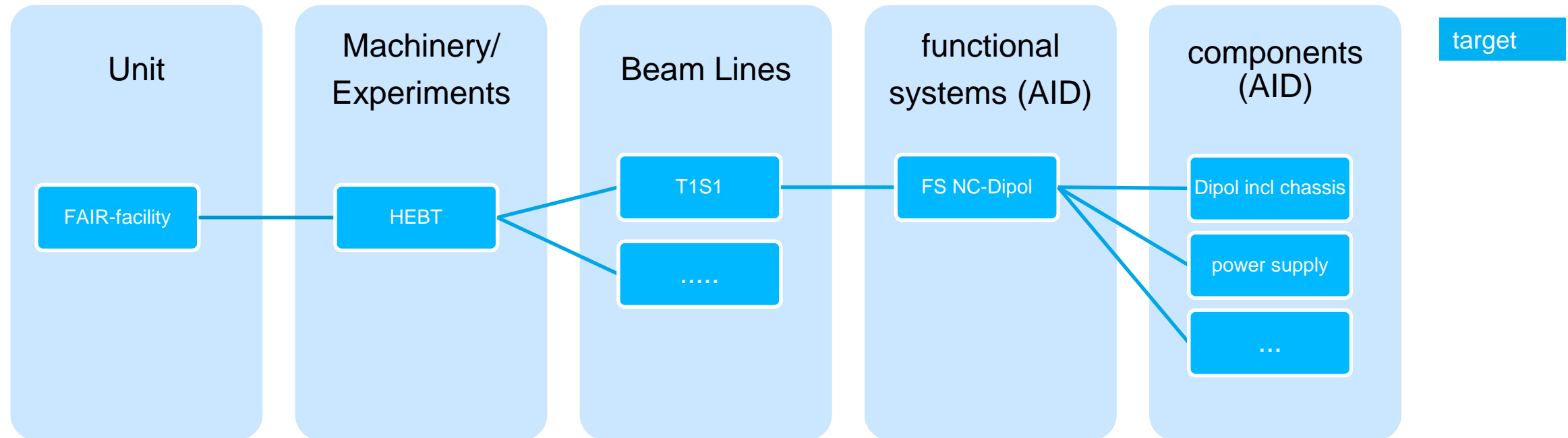
difficulty breathing, asphyxiation

poisoning

Evidence of Conformity

Transition development - implementation

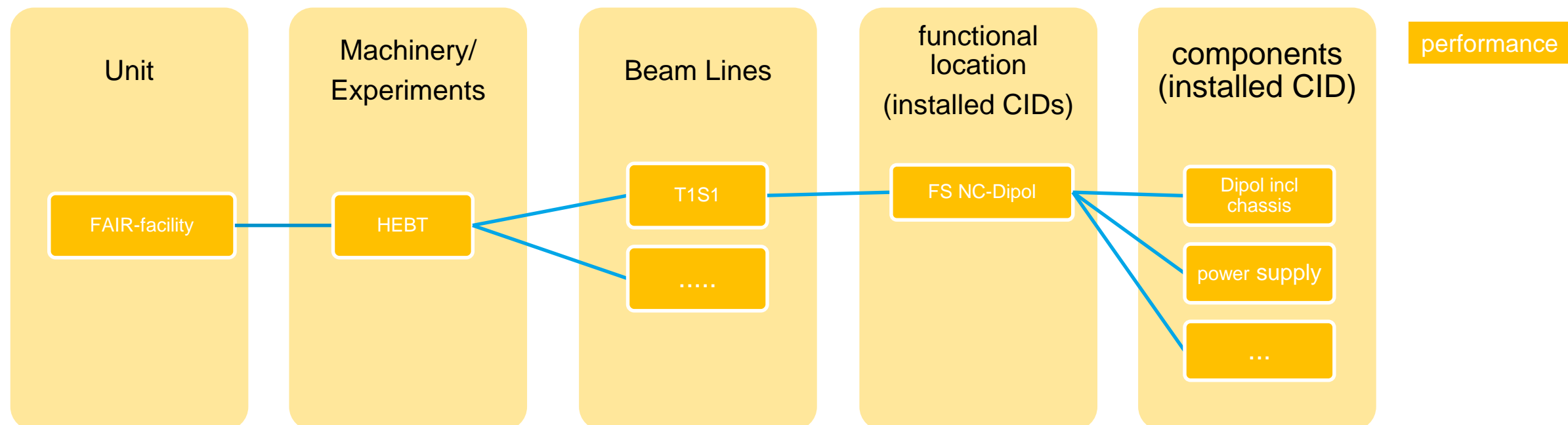
Development



IOL ---- parts list (AID-Listen) ---- risk evaluation --- measure plan ----- preparing checklists

functional location ----- Lists of installed components (CID-Listen) ---- finished checklists for functional location or CID

Implementation



Technical documents of Machine Directive:

- general description of the machinery
- layout drawing machinery
- control circuit diagrams
- description and explanations
- complete detailed drawings, possibly with calculations, test results, certificates, etc., which are necessary for checking the compliance of the machine with the basic safety and health protection requirements
- documents of the risk assessment (required by FAIR / GSI in accordance with GS)
- List of essential requirements
- Description of the measures
- Applied standards and technical specifications
- Technical reports with results of the test
- operation instructions of the machinery (content on separate foils)
- if necessary: declaration of incorporation for partly completed machineries built into the machinery
- if necessary: assembly instructions for built-in partly completed machineries
- if necessary: EC declaration of conformity for built-in machineries/ products
- copy of the declaration of conformity
- in the case of series production, a list of the measures taken internally to ensure compliance of all manufactured machineries with the provisions of this directive
- audit reports, test reports and acceptance reports which are necessary to determine that the machinery can be safely assembled and put into operation due to its design or construction.

The EC declaration of conformity must contain the following information:

1. company name and full address of the manufacturer and, if applicable, his authorized representative;
2. Name and address of the person, authorized to compile the technical documents; this person must be a resident of the community;
3. description and identification of the machinery, including general name, function, model, type, serial number and trade name
4. a sentence in which it is expressly declares, that the machine complies with all relevant positions of this directive and, if applicable, a similar sentence in which the conformity with other directives and / or relevant provisions to which the machinery conforms, is declared. These references must be those of the texts published in the Official Journal of the European Union.
5. if applicable, the name, address and identification number of the specified location, which executed the EC type-examination procedure listed in Annex IX, as well as the number of the EC type-examination certificate;
6. if applicable, the name, address and identification number of the specified location, that approved the full quality system referred to in Annex X
7. if applicable the references of the harmonized standards, applied in accordance with Article 7 paragraph 2
8. if applicable, the references of the other technical standards and specifications applied
9. place and date of the declaration;
10. information of the person, who is authorized to issue this declaration on behalf of the manufacturer or his representative, as well the signature of this person

Contents of the operation instructions of Machine Directive:

- business name and address
- designation of the machinery
- EC declaration of conformity
- General description of the machinery
- the drawings, diagrams, descriptions and explanations necessary for the use, maintenance and repair of the machine and for checking its correct functioning.
- workstations
- intended use
- warnings regarding misuse of the machinery that experience has shown might occur
- Instructions for the assembly, construction and connection of the machinery, including the drawings diagrams and the means of attachment and the designation of the chassis or installation on which the machinery its to be mounted.
- instructions relating to installation and assembly for reducing noise or vibration
- instructions for the putting into service and use of the machinery and, if necessary, instructions for the training of operators
- information about the residual risks that remain despite the inherent safe design measures, safeguarding and complementary protective measures adopted
- instructions on the protective measures to be taken by the user, including, where appropriate, the personal protective equipment to be provided,
- the essential characteristics of tools which may be fitted to the machinery;
- the conditions in which the machinery meets the requirement of stability during use, transportation, assembly, dismantling when out of service, testing or foreseeable breakdowns;

Contents of the operation instructions of Machine Directive:

- instructions with a view to ensuring that transport, handling and storage operations can be made safely, giving the mass of the machinery and of its various parts where these are regularly to be transported separately
- the operating method to be followed in the event of accident or breakdown; if a blockage is likely to occur, the operating method to be followed so as to enable the equipment to be safely unblocked;
- the description of the adjustment and maintenance operations that should be carried out by the user and the preventive maintenance measures that should be observed;
- instructions designed to enable adjustment and maintenance to be carried out safely, including the protective measures that should be taken during these operations;
- the specifications of the spare parts to be used, when these affect the health and safety of operators;
- the following information on airborne noise emissions:
 - the A-weighted emission sound pressure level at workstations, where this exceeds 70 dB(A); where this level does not exceed 70 dB(A), this fact must be indicated,
 - the peak C-weighted instantaneous sound pressure value at workstations, where this exceeds 63 Pa (130 dB in relation to 20 μ Pa),
 - the A-weighted sound power level emitted by the machinery, where the A-weighted emission sound pressure level at workstations exceeds 80 dB(A).
- where machinery is likely to emit non-ionising radiation which may cause harm to persons, in particular persons with active or non-active implantable medical devices, information concerning the radiation emitted for the operator and exposed persons
- Furthermore, machinery designed and constructed for use in a potentially explosive atmosphere must be marked accordingly.
- All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service.

Scope of the assembly instructions for an incomplete machinery:

The assembly instructions for partly completed machinery must contain a description of the conditions which must be met with a view to correct incorporation in the final machinery, so as not to compromise safety and health.

The assembly instructions must be written in an official Community language acceptable to the manufacturer of the machinery in which the partly completed machinery will be assembled, or to his authorised representative

Thank you for your attention