

Production Line Compliance Assurance

A White Paper by SGS Manufacturing & Processing Industries Services

October 2023

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Introduction

PRODUCTION LINES, CAPEX PROJECTS & COMPLIANCE

Investments in new production lines (on existing and new sites) need to be assured at several levels:

- Quality
- Performance
- Timeliness
- Compliance

SGS offers solutions for all aspects of CAPEX assurance, from design to procurement, to construction and commissioning. The topic of this document, however, is compliance assurance. Compliance assurance is particularly important, because without it permits to operate will not be delivered by local authorities. Safety compliance for production lines is an integrated concept which does not pertain only to individual machines or equipment, but encompasses the overall production line and its operation.

Compliance is to be considered within the following contexts:

- Type of operation(s) and owner's operations planning
- Type of machines (tied to above point)
- Applicable legislation and standards

As such, every production line project is different and requires an integrated and managed approach from planning to commissioning, to provide comprehensive compliance assurance to the project owner. Based on experience, SGS finds that a fairly standard methodology can be applied to the approach, grounded in ISO standards.

FULFILLING REGULATORY COMPLIANCE ("CERTIFICATION") FOR NEW PRODUCTION LINES

In one form or degree, most countries have a regulatory system to ensure that production lines put in place be safe. In general, this happens through a combination or (independent) review of production line design and set-up as well as certification requirements on individual pieces of equipment (machines, industrial equipment such as boilers or hydraulic systems, etc.).

For example, in the EU, the EU basic laws are translated into Directives or Regulations (Pressure Vessel, ATEX, Machinery, etc.) that apply to individual pieces of equipment for certification purposes, i.e., controlling market access for these goods.

At the next level, the EU basic laws are then translated into national or provincial regulations that govern the safety compliance assurance of production lines (or portions of the lines).

Similar approaches exist in the Russian Federation (through the EAC or "GOST" standards framework), the US, etc.

Although regulations differ from country to country, as well as technical standards, there is a fundamental similarity in all approaches and SGS proposes to deploy a homogeneous method to address production line safety compliance assurance.

Production line safety compliance assurance

FRAMEWORK

ISO has produced a framework of standards with the objective to enable comprehensive and effective assessment and improvement of safety for production systems.

One of these is ISO 11161, on the safety of integrated manufacturing systems (IMS), or production lines. A type-B standard, it provides a solid framework for the analysis and assessment of production lines and is grounded in the ISO families of standards.

ISO 11161 considers that a production line is a system of (potentially interconnected) integrated manufacturing systems ("production cells"). The standard specifies the safety requirements for Integrated Manufacturing Systems (IMS) that incorporate two or more interconnected machines for specific applications, such as component manufacturing or assembly. It gives requirements and recommendations for the safe design, safeguarding and information for the use of such IMSs.

SGS finds that following the ISO 11161 approach to develop the analysis, assessment, and potential correction/improvement of safety features of production lines is logical and effective. The standard refers to other more specific ISO standards and can be leveraged using local/regional regulations as a basis for providing safety compliance assurance.

For purposes of information, the ISO standards below (and their local/regional versions for compliance purposes) are to be considered when using this methodology:

- ISO 12100-1:2003, Safety of machinery — Basic concepts, general principles for design — Part 1: Basic terminology, methodology
- ISO 12100-2:2003, Safety of machinery — Basic concepts, general principles for design — Part 2: Technical principles
- ISO 13849-1:2006, Safety of machinery — Safety-related parts of control systems — Part 1: General principles for design
- ISO 13849-2:2003, Safety of machinery — Safety-related parts of control systems — Part 2: Validation
- ISO 13850:2006, Safety of machinery — Emergency stop — Principles for design
- ISO 14120:2002, Safety of machinery — Guards — General requirements for the design and construction of fixed and movable guards
- ISO 14121:1999, Safety of machinery — Principles of risk assessment
- ISO 14122-1:2001, Safety of machinery — Permanent means of access to machinery — Part 1: Choice of a fixed means of access between two levels
- ISO 14122-2:2001, Safety of machinery — Permanent means of access to machinery — Part 2: Working platforms and walkways
- ISO 14122-3:2001, Safety of machinery — Permanent means of access to machinery — Part 3: Stairways, stepladders, and guard-rails
- ISO 14122-4:2004, Safety of machinery — Permanent means of access to machinery — Part 4: Fixed ladders
- IEC 60204-1:2005, Safety of machinery — Electrical equipment of machines — Part 1: General requirements
- IEC 62061:2005, Safety of machinery — Functional safety of safety-related electrical, electronic, and programmable electronic control systems

The above list is not exhaustive and additional technical standards can/will be added, specifically those mentioned as a basis for consideration in the EU legislation (PED, Machine Directive, EMC, Low Voltage Directive, Lifting Devices Directive, ATEX, Seveso, etc.), US regulations (NRTL, OSHA, ASME, API, etc.), and others.

We have compiled a comprehensive list of relevant standards (see Appendix), which SGS has used across several projects.

APPROACH

Attaining safety compliance assurance is an iterative process. It is the responsibility of the “integrator”, or the entity in charge of designing, assembling, procuring, and commissioning the production line.

Thorough application of the ISO 11161 standard approach requires in-depth analysis of the IMSs, down to individual pieces of equipment, aiming to assess and minimize risks. To do so, Type B & B1 as well as Type C standards will be used.

The integrator shall consult with the user and the suppliers of the component machines and associated equipment to achieve safety compliance. Safety compliance is a directional concept, which goes from the whole production line to the IMSs to individual equipment.

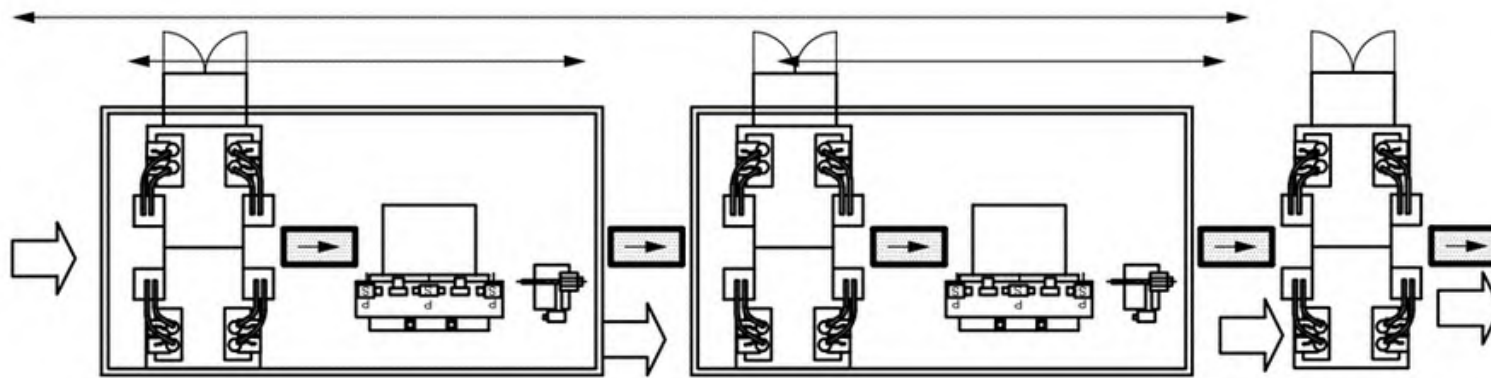


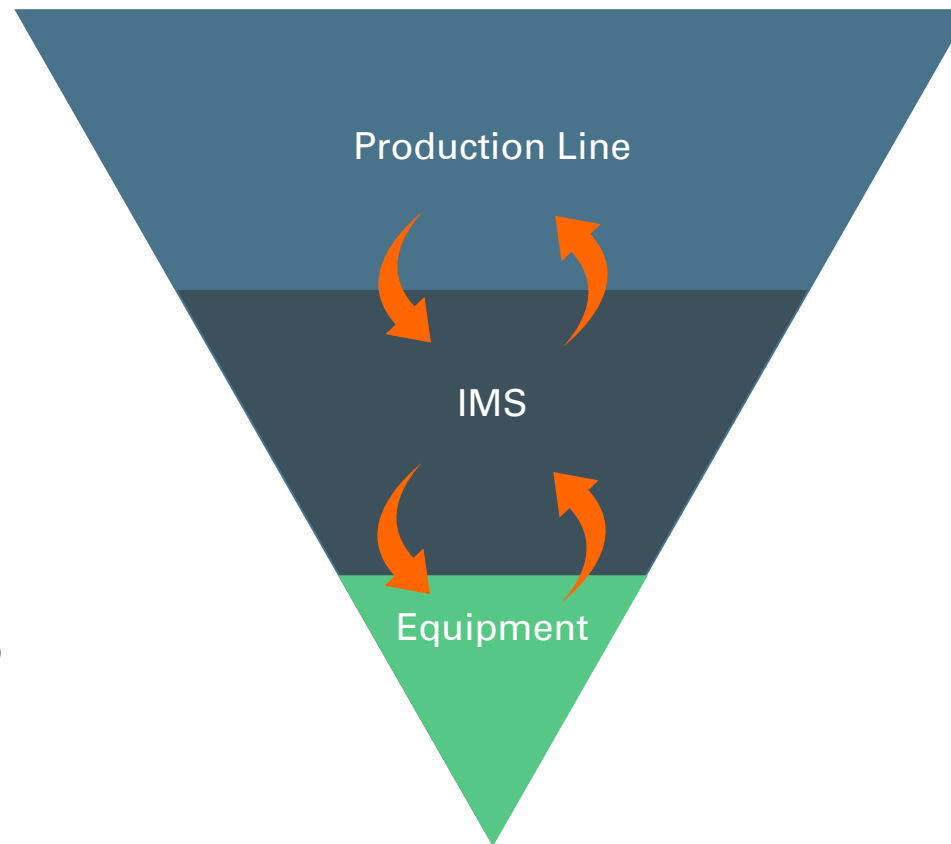
Fig 1: example of a production line made of 3 IMSs – ISO 11161 (each equipment may be provided by a different supplier – provided it complies with safety compliance requirements)
Source: EN ISO 11161:2007/A1:2010. Safety of machinery — Integrated manufacturing systems — Basic requirements. Amendment 1 (ISO 11161:2007/Amd 1:2010)

The safety requirements at production line level and the way a production line is divided into different IMSs will then structure the requirements for operations and maintenance, but also type of equipment, additional safety equipment, interface management and ultimately the specifications for the equipment to be procured (CE marking, specific control guards, etc.), and the IMSs assembly and commissioning.

The cascading of safety compliance requirements and how they translate into fabrication and/or commissioning and installation instructions. The figure below explains this concept:

Activities

- Analysis of production line
 - Identification of IMSs
 - Interfaces & overall line assessment
 - Risk estimation & evaluation
 - Protective measures
 - Validation of protective measures
-
- Specification of the IMS
 - Identification of hazards and hazardous situations
 - Interfaces
 - Risk estimation & evaluation
 - Protective measures
 - Validation of protective measures
-
- Equipment safety requirements (supplier responsibility, to be stated in specifications)
 - ATEX
 - Pressure vessel
 - EMC
 - Functional safety
 - Machine safety



Outputs

- Safety policy/instructions for plant
 - Fire safety, structural safety
 - Overall control
 - General Map (digital twin/similar)
 - Emergency plans
-
- Map of IMSs
 - Map of interfaces
-
- IMS safety manual
 - IMS safety assurance support document
 - Emergency plans
 - O&M instructions (safety)
-
- Derived specific equipment safety requirements
 - Commissioning requirements
-
- Equipment safety manual
 - IMS integration manual
 - Safety assurance support document
-
- Equipment specs
 - O&M manual
 - Supplier instructions
 - Operational KPIs

Fig 2: schematic of safety compliance assessment and assurance for a production line – following ISO 11161

SGS will support this process at all stages, from planning and design to final commissioning, and works alongside all actors in the value chain. SGS serves as an independent reviewer of the IMS definitions and specifications, as well as of the risk evaluation and mitigation proposed.

SGS will assure safety compliance at all levels (equipment, IMS, production line) by providing independent supervision, assessment, and reporting.

The actual detailed delivery plan will depend of course on the type of production line and the location, and the applicable legislation.

Example methodology & organization, with case studies

EXAMPLE METHODOLOGY & ORGANIZATION

As an example, the following paragraphs describe a typical organization of SGS services for the evaluation and verification of CE (EU and local) regulations applicable to the industrial production line(s) of a battery production factory to obtain CE marking, according to the local requirements for environmental and industrial health and safety in an EU country.

The activities described and developed below would be applied on the production line(s) and carried out remotely (desktop) and on site.

In this example, a preliminary analysis of the list of equipment to be installed resulted in the following standards, regulations and documents (in addition to local regulations) that should be followed:

- Machinery directive 2006/42 / CE
- Low voltage directive 2014/35 / CE
- EMC directive 2014/30 / CE
- Pressure equipment directive 2014/68 / EU
- New approach directives in force, for the CE marking of products
- Harmonized standards in force published in the official journal of the European Union with reference 2016 / C 014/01
- SGS Group Quality Manual
- Generic activity procedures as a Control Body

The activities as would be developed by SGS are set out in the following stages, clearly differentiated and consecutive:

STAGE I. DESIGN REVIEW, SUPPLIERS CONTROL AND ISSUANCE OF CRITICAL POINTS DOCUMENT

The client would provide SGS with all the available documentation (design, specifications, operational plan) to establish:

- The safety compliance concept, based on an ISM definition and analysis, to be documented and validated by the client, as a basis for all subsequent documentation.
- The points of control and inspection of suppliers, as well as the criteria to apply, to assure compliance at the reception phase of the installation, in accordance with the CE Marking process.
- An equipment requirements document, which would contain points to be considered at the reception and start-up of the installation to ensure CE marking of the whole production line. This document would be based on the standards mentioned above.
- A documented review of equipment/supplier requirements (part of the customer procurement process).

The SGS systematic approach for the control of suppliers to guarantee the CE marking of each machine, partly completed machinery, assembly of machines, interchangeable equipment or lifting accessories, is described below:

1. Validation of the proposed designs, in all cases considering the harmonized EN standards applicable as reference, under the different applicable CE marking directives.
At this point, the categorization of the different equipment and lines under pressure under the criteria of Directive 2014/68 / EU is a priority task within this phase, due to the criticality.
2. Validation of the provided documentation, emphasizing compliance with the CE conformity statements delivered and in the use and maintenance manuals. SGS would take as reference the needs set out in Annex II and Annex I of Directive 2006/42 / EC.

SGS would issue a report of each analysis where any non-conformities detected would be indicated to ensure compliance with the Directive of the delivered machines.

SGS affiliates are able to provide support to suppliers to ensure all criteria be met before equipment are released for shipping to final location.

STAGE II. PRELIMINARY INSPECTION

SGS would carry out a preliminary inspection on site at the project location before the machines are installed or put in service to verify that all of them meet the requirements of the Machinery Directive 2006/42/CE and the manufacturers have complied with the information established in the previous stage.

This stage can be reduced or eliminated if some of the inspections are executed at suppliers' sites by local SGS teams qualified for CE marking inspection.

The purpose of this inspection is to identify potential technical non-conformities of the machines to immediately put in place corrective actions (before commissioning) and hence assure compliance with the applicable regulations.

Findings and conclusions would be documented by SGS and provided as an independent third-party report, to support CE marking and/or local regulation certification.

STAGE III. COMMISSIONING VERIFICATION OF COMPLIANCE WITH MACHINERY DIRECTIVE REQUIREMENTS AND EN 13849-1:2015

At commissioning, inspection and functional testing would be carried out to certify the compliance with Machinery Directive 2006/42/EC. During this inspection, SGS collects all documentation involved in the safety functions as well as its electrical architecture, to check that they all follow the requirements established in the standard EN 13849-1: 2015.

For safety devices, SGS would evaluate their aptitude to perform the safety function in the foreseeable conditions and determine that performance levels are at least equal to the required performance levels specified in the standard.

To verify compliance with EN 13849-1:2015 standard, SGS uses software (of the German IFA, for example).

To provide independent third-party assurance, SGS may witness the following:

- Electrical safety testing, to comply with the Directive 2014/35/UE
- Electromagnetic compatibility testing, to comply with the Directive 2014/30/UE
- Acoustic testing
- Non-destructive testing in welds or critical structural elements

Full compliance with EN ISO 13849-1:2015 requires independent validation of safety functions in accordance with EN ISO 13849-2:2012.

SGS would perform:

- Validation of the safety functions
- Validation of categories
- Validation of environmental requirements
- Validation of maintenance requirements

In the case that the safety functions depend on an automated or programmable relay, it will be necessary to perform a validation of that software as well. For full validation to EN ISO 13849-1:2015, a software validation report issued by a third party that was not involved in the design of the safety functions may be needed, which SGS can perform.

The validation report would include at least:

- A clear and unambiguous specification setting out the security performance to be achieved by the software
- Evidence that the software has been designed to achieve the required safety performance
- Details of the tests carried out to prove the required safety performance

The validation performed by SGS would be done by accessing the safety software and the following activities:

- Verification of activation and operation of function coverage diagnostics
- I/O tests to ensure compliance with the security matrix defined in the risk analysis
- Checking of recognition or reset functions

The validation of the software would be performed by means of an analysis of the software prior to the inspection, using a safety matrix provided by the client and by means of in-situ tests, taking advantage of the inspection visit to the machine.

The client must provide a copy of the safety software installed on the machine as well as the safety matrix used for its development. SGS would not perform any uploading/downloading, nor any modifications or compilations of the software.

A report should be issued summarizing all elements and findings as an independent third-party verification proof, providing all non-conformities that need to be addressed before Stage IV.

STAGE IV. FINAL VERIFICATION OF COMPLIANCE WITH MACHINERY DIRECTIVE REQUIREMENTS AND EN 13849-1:2015

Once the non-conformities identified in the previous stages are resolved, a final inspection would be carried out to certify the compliance with Machinery Directive 2006/42/EC. This inspection is needed to issue the Declaration of Conformity EC according to the Directive and final report by SGS.

STAGE V. DRAFTING OF THE TECHNICAL CONSTRUCTION FILE

SGS would draw up all necessary documents required for the preparation of a Technical File of the complete production line and subsystems.

The Technical File of the final installation should be drawn up from all documentation provided by the client and according to the guidelines referred to in Annex VII of the machinery directive 2006/42/EC, including the analysis and risk assessment associated with the installation.

The documentation issued by SGS, as an integral part of the Technical File, would be the following:

- Risk assessment according to standard EN 12100 and series of standards EN 1034
- List of justification of the essential health and safety requirements which apply to the machinery
- Justification of standards and other technical specifications used
- Compliance with Annex III of the directive 2006/42/EC (CE MARKING), and layout
- Type model of a Declaration of Conformity in accordance with Annex II to the Directive (Declarations)
- Justification document in compliance with EN 13849-1:2006

The rest of the documentation required for the elaboration of the Technical File, which must be provided by the manufacturer, would be the following:

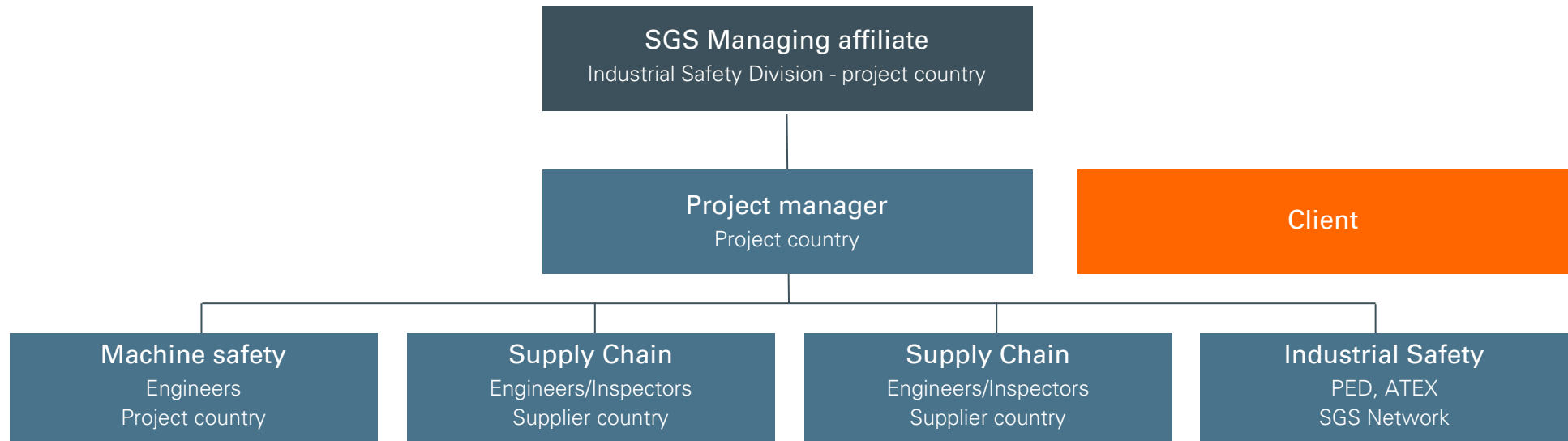
- General description of the production line.
- Overall drawing of the machinery and drawings of the control circuits
- Detailed drawings
- User Manual for the Production Line, according to paragraph 1.7.4 of Annex I to Directive 2006/42/EC, which will be revised and completed by SGS in its case
- Control circuits, electric, hydraulic, and pneumatic
- Test according to EN 60204-1:2006
- Declarations of conformity or approvals of components/individual machines

All the documentation provided would be evaluated by SGS to check its compliance with the Machinery Directive.

Finally, the client would be able to issue the Declaration of Conformity EC and put the EC marking on the plate of the whole production line.

This obligation is defined by the Machinery Directive 2006/42 / EC, so in case the Client has not been defined as the figure of the final integrator of the production line (subject to CE marking), SGS would assume this role.

To perform these tasks, SGS will set up a project organization mirroring the Client's organization. Typically, the organization would look as per figure below:



CASE STUDIES

CE MARKING ASSESSMENT | CAN PRODUCTION LINE | FRANCE AND SPAIN

Scope of work:

- CE Marking Assessment
- Determine which EU directives and standards apply to the can production line
- Supplier supervision
- Risk assessment according to EN 12100 and EN 619
- Performance Levels Calculations, according to EN 13849-1
- Safety Software Validation
- Issuance of the Technical File and global CE Marking documentation assessment
- CE Marking Training

PAPER MACHINE CE MARKING | PAPER PRODUCER | SPAIN

Scope of work:

- CE Marking Assessment
- Determine which EU directives and standards apply to the paper production line
- Supplier supervision
- Pressure equipment and pressure pipelines categorization, according to 2014/68/EU
- Risk assessment according to EN 12100 and EN 1034
- Performance Levels Calculations, according to EN 13849-1
- Safety Software Validation
- Issuance of the Technical File and global CE Marking documentation assessment
- CE Marking Training
- Local statutory industrial requirements assessment

REGULATORY ASSURANCE | ETHYLENE CRACKER | BELGIUM

Scope of work:

- Regulations compliance support; high investment, high complexity
- Safety, environmental, legal and compliance regulatory assurance
- Offer a one-stop-shop and subject matter expertise
- Single point of contact for all regulatory mapping and compliance, including:
 - EU Directive (PED, SPVD, LVD, MD, EMC, MID, ATEX), including CE marking and notified body
 - Construction Product Regulations (CPR)
 - Chemical regulations (RoHS, CLP, REACH)
 - Industrial Emissions Directive (IED)
 - H&S legislation (CODEX, AREI/RGIE, VLAREM, VLAREBO)
 - Environmental Impact Assessment
 - Major Accident Hazards - Seveso III
 - Belgium Cooperation Agreement
 - Tank Park Guideline Antwerp
 - Functional safety expertise



Appendix

RELEVANT STANDARDS FOR PRODUCTION

- EN ISO 12100:2010. Safety of machinery - General principles for design – Risk assessment and risk reduction (ISO 12100:2010)
- EN ISO 13854:2019. Safety of machinery - Minimum gaps to avoid crushing of parts of the human body (ISO 13854:2017)
- EN 547-1:1996+A1:2008. Safety of machinery - Human body measurements - Part 1: Principles for determining the dimensions required for openings for whole body access into machinery
- EN 614-1:2006+A1:2009. Safety of machinery - Ergonomic design principles - Part 1: Terminology and general principles
- EN 894-1:1997+A1:2008. Safety of machinery - Ergonomics requirements for the design of displays and control actuators - Part 1: General principles for human interactions with displays and control actuators
- EN ISO 14118:2018. Safety of machinery - Prevention of unexpected start-up (ISO 14118:2017)
- EN 1837:2020. Safety of machinery - Integral lighting of machines
- EN ISO 11688-1:2009 Acoustics – Recommended practice for the design of low noise machinery and equipment – Part 1: Planning (ISO/TR 11688-1:1995)
- EN 60204-1:2006. Safety of machinery - Electrical equipment of machines - Part 1: General requirements
- EN - ISO 4413:2010. Hydraulic fluid power - General rules and safety requirements for systems and their components (ISO 4413:2010)
- EN ISO 4414:2010. Pneumatic fluid power - General rules and safety requirements for systems and their components (ISO 4414:2010)
- EN ISO 13732-1:2008. Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 1: Hot surfaces (ISO 13732-1:2006)
- EN ISO 13849-1:2015. Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design (ISO 13849-1:2015)
- EN ISO 13850:2015. Safety of machinery - Emergency stop function - Principles for design (ISO 13850:2015)
- EN ISO 13855:2010. Safety of machinery - Positioning of safeguards with respect to the approach speeds of parts of the human body (ISO 13855:2010)
- EN ISO 13857:2019. Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs (ISO 13857:2019)
- EN ISO 14119:2013. Safety of machinery - Interlocking devices associated with guards - Principles for design and selection (ISO 14119:2013)
- EN ISO 14120:2015. Safety of machinery - Guards - General requirements for the design and construction of fixed and movable guards (ISO 14120:2015)
- EN 1127-1:2019. Explosive atmospheres — Explosion prevention and protection — Part 1: Basic concepts and methodology
- EN ISO 14122-1:2016. Safety of machinery - Permanent means of access to machinery - Part 1: Choice of fixed means and general requirements of access (ISO 14122- 1:2016)
- EN ISO 14122-2:2016. Safety of machinery - Permanent means of access to machinery - Part 2: Working platforms and walkways (ISO 14122-2:2016)
- EN ISO 14122-3:2016. Safety of machinery - Permanent means of access to machinery - Part 3: Stairs, stepladders and guard-rails (ISO 14122-3:2016)
- EN ISO 14122-4:2016. Safety of machinery - Permanent means of access to machinery - Part 4: Fixed ladders (ISO 14122-4:2016)
- EN ISO 14738:2008. Safety of machinery Anthropometric requirements for the design of workstations at machinery (ISO 14738:2002)
- EN 619:2022. Continuous handling equipment and systems - Safety requirements for equipment for mechanical handling of unit loads
- EN 620:2021. Continuous handling equipment and systems - Safety requirements for fixed belt conveyors for bulk materials.
- EN ISO 11161:2007/A1:2010. Safety of machinery — Integrated manufacturing systems — Basic requirements. Amendment 1 (ISO 11161:2007/Amd 1:2010)

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