SAFEGUARDS
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MACHINERY DIRECTIVE AND SAFETY STANDARD TRANSITION PERIODS TO EXPIRE IN 2009

FIRST WAKE-UP CALL - REVISED MACHINERY DIRECTIVE 2006/42/EC TO REPLACE 98/37/EC

The current Machinery Directive has ensured a common policy of safety and supply of machinery across the European Economic Area (EEA) for over 10 years. In 2006, a comprehensive amendment was adopted and 2006/42/EC will replace the provisions of the existing Directive, from 29 December 2009.

The Machinery Directive sets out the procedures that manufacturers must conform to with certain essential health and safety requirements. Machinery that conforms to all relevant requirements can then carry the CE mark, showing compliance with the Machinery Directive and all other relevant Directives.

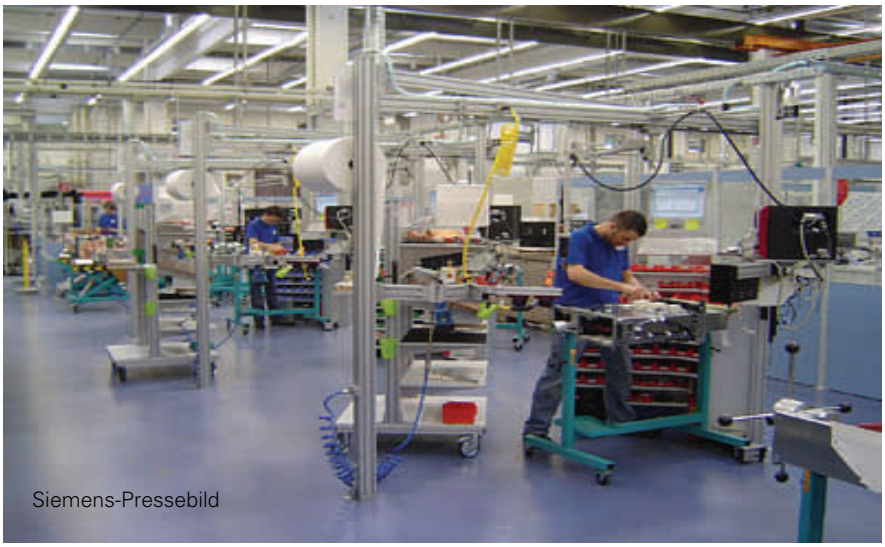
Major consequences of the new Directive include:

- A risk assessment, instead of a hazard analysis, has to be carried out according to additional requirements and documented. Documentation may have been disregarded or risk assessments may not have fulfilled the complete requirements ISO 14121 "Safety of machinery – risk assessment", providing a risk to businesses who are not prepared.
- A declaration of incorporation of partly completed machinery must be provided (refer to 2006/42/EC article 13 (c) and annex II).
- Assembly instructions for partly completed machinery have to be provided (refer to 2006/42/EC article 13 (b) and annex VI), together with the technical documentation (refer to 2006/42/EC article 13 (a) and annex VII part B).
- The borderline issue with the Lifts Directive has been clarified and this has to be considered accordingly.
- The manufacturer will be able to certify the conformity of the machinery himself, if his machinery is Annex IV machinery and designed according to harmonized standards covering all the relevant essential requirements (refer to 2006/42/EC article 12 (3b) and annex VII or to article 12 (3c) and annex X).
- The manufacturer of other machinery than Annex IV defined machinery will be able to choose between an EC type-examination by a Notified Body and an approval by a Notified Body of his full quality assurance system.

In addition to the amendments of the Machinery Directive, other standards have also been enhanced. It is essential that the most up-to-date version of the product standard is applied.

SECOND WAKE-UP CALL—EN ISO 13849-1 STANDARD FOR MACHINERY CONTROL SYSTEM TO REPLACE EN 954-1

This year, EN 954-1 will be finally be fully replaced by EN ISO 13849-1 "Safety of machinery – Safety-related parts of control systems – Part 1: General principles for design". The new standard reflects the increased tendency to use electronic and programmable systems for safety functionality.



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The new standard was published in November 2006, during which the standard EN 954-1 can continue to be used in parallel for a three-year transition period, expiring 30th November 2009. For more complex architectures, which are not mentioned in the EN ISO 13849-1, the EN 62061 "Safety of machinery—Functional safety of safety -related electrical, electronic and programmable electronic control systems" has to be applied.

EN ISO 13849-1 defines, in addition to the proven categories as defined in the current EN 954-1, additional requirements for programmable electronic systems and introduces performance levels (PL) in the following areas:

- Hardware architectural constrains according:
  - structure
  - diagnostic coverage
  - common cause failure
- Quantitative requirements, i.e. hardware reliability per safety function:
  - $MTTF_D$ (i.e. Mean Time to Dangerous Failure) values
- Hardware and Software qualitative requirements according:
  - behavior of safety functions under fault conditions
  - safety-related software
  - systematic failures
  - environmental conditions

The required performance level is the result of the risk assessment and is graded from "a" (very low risk) up to "e" (high risk).

A required performance level can only be reached if the appropriate quantitative and the qualitative requirements are fulfilled.

The consequences of the new additional requirements are:

- suppliers have to deliver B10 or $MTTF_D$ for their components,
- failure rates must be calculated per safety function to prove the performance level,
- requirements for safety-related software have to be fulfilled and documented if applicable.

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