

## The genesis and evolution of the basic standards for machinery safety

The following page aims to provide background information about the revision process of four basic technical documents, around which the ETUI-REHS has been trying to promote and coordinate a trade union focus both at national and European level. It also provides substantial information about the genesis of EN 292, the "core" of the system of European standards elaborated in support of the Machinery Directive.

**From EN 292: 1991 *Safety of machinery – Basic concepts, general principles for design* – Part 1: basic terminology, methodology – Part 2: technical principles and specifications to EN ISO 12100-1/-2:2003**

### Origin of EN 292

In 1985, when they started working together in the recently set-up CEN TC114 /WG1, the experts sent by the CEN Member Bodies brought with themselves the technical culture of each one's country, including a good knowledge of the national regulations and national standards relating to machinery safety, together with the knowledge of how the proposals for the Machinery Directive were evolving in the Commission / Member States / Working Groups in Brussels.

They rapidly agreed that the forthcoming fundamental standard should follow the basic concepts in Annex I of the Machinery Directive in addition to drawing its provisions from a selection of the most valuable concepts that were developed in several of these national documents. It would give added value to section 1.1 of Annex I and become the first Harmonised Standard in support of the Machinery Directive.

The concept of the A/B/C structure came much later as the potential for a large number of standards in the programme became apparent.

The basic purpose of the standard would be to interpret the legal requirements of Annex I of the Machinery Directive – in particular Section 1.1 – in a way that would be useful to designers and other people involved in machinery safety wishing to meet the requirements of the Machinery Directive.

With this in view, the Drafting Group (Paul Makin, HSE – Siegfried Radandt, Berufsgenossenschaft "Nahrungsmittel und Gaststätten" – Oddone Beltrami, STANIMUC – J.-P. Lacore, INRS) quickly built up the first working document from national standards that had been developed following the same principles. The same information sources were being used by the Commission / Council Working Groups and Annex I of the Directive and EN 292 evolved together over the next few years.

### Main features of EN 292

Part 1 of EN 292 essentially deals with terminology and design methodology.

Convinced of the importance of using precise terms to express well-defined concepts in the whole set of forthcoming European machinery-safety standards, and observing that the draft Machinery Directive – which was being elaborated in parallel with EN 292 – did not take much care of terminology, the members of CEN TC114/WG1 deliberately decided to compensate for this deficiency by selecting and defining more than 50 basic concepts, gathered in Clause 3 of EN 292-1.

Selecting equivalent terms and harmonizing their definitions in English, German and French (the three official languages of CEN) revealed itself as a very fruitful exercise.

Regarding the most effective method to design safe machinery, the sequence "inherently safe design – safeguarding – information for use" had already been more or less formally used in various countries, but EN 292 had the merit to express it, under the denomination "three-step method", in a very precise and pedagogical form.

Last, but not least, EN 292 highlighted the fundamental role of the risk assessment at the origin of every attempt to reduce risk and defined the basis for the elaboration of another fundamental standard entirely devoted to risk assessment : EN 1050.

Between 1985 and 1989, several experts involved in the elaboration of EN 292 were also involved in that of the Machinery Directive, so that a satisfactory "coupling" could be obtained between the methodological requirements of the directive and the methodological provisions of EN 292

In its introduction, EN 292 states "*It is recommended that this standard be incorporated in training courses and manuals to convey basic terminology and general design methods to designers*". In several countries, experience over 15 years has proven that this recommendation did not go unheeded.

Part 2 of EN 292 sets out technical principles in relation with each step of the "3-step method" defined in Part 1 and illustrated the diagram at the end of the document.

### **The revision of EN 292:1991: a better platform for machinery safety**

In February 1995, CEN/TC 114 Safety of Machinery and ISO/TC 199 Safety of Machinery decided to revise EN 292 in the context of the Vienna Agreement (regulating technical cooperation between ISO and CEN) under CEN's leadership. As a result, a Special Working Group (which held its first meeting in November 1995) consisting of experts from ISO, CEN, IEC and CENELEC discussed the comments received from the public inquiry carried out in CEN (on prEN 292) and in ISO (on DIS 12100). The new standard EN ISO 12100 was adopted in 2003, and published in the Official Journal of the EU at the end of 2005.

The ETUI-REHS was a member of the Special Working Group (SWG) revising EN 292. The process was time- and resource-consuming, as reflected by the number of meetings held by the SWG. The cooperation between CEN and ISO brought together a large number of technical experts from all over the world to endeavour to agree on common technical solutions to identified problems. Different safety philosophies emerged over the years, and crucial elements like risk perception and social acceptance of risk, roles of the designer and of the user in applying safety principles, risk-damage causality, state of the art, human-technology interaction (need to keep pace with technological and social development), among others, represented sticking points where different views clashed.

The revision process resulted in EN ISO 12100-1/-2:2003

### **The value added to EN 292 by the revision process**

As was foreseeable, widening the debate on the revision of EN 292:1991 to non-European countries raised extremely interesting – sometimes passionate – discussions on basic issues. This resulted principally, in EN ISO 12100:2003, in the following innovations and improvements :

- Harmonized views on the allocation of designer's and user's roles (and responsibilities) in the design of machinery

The European approach to this, which allocates a pre-eminent role to the designer, took the US experts somewhat aback, as illustrated by a remark made in the first inquiry and qualifying it as a "quirk". The discussions ignited by the US proposals, which initially tended to disregard the European approach, resulted in the following amendments to the 1991 version, the new version remaining in line with the European approach whilst acknowledging the feedback from the user :

- the two spheres (of designer and user) are depicted as more evenly balanced, although design is symbolically portrayed as being more important than use;
- the new representation brings out the *user's input to machinery design* and the *designer's contribution to its safe use*;
- important clarification is provided by four notes located under the schematic representation of the designer's and user's roles.

The concepts of *residual risk after protective measures have been taken by the designer* and *risk remaining after all protective measures have been taken* gave rise to protracted and heated discussions.

- Detailed provisions about the concept of *adequate risk reduction* (i.e the reduction of risk to the lowest practicable level, in ways which do not adversely affect other aspects of use).

During the revision process the use of the term "tolerable risk" – taken from ISO Guide 51 – was considered and ultimately rejected. It was the subject of much heated debate within the WG. Some Members considered that it was a useful concept that moved the debate along from "adequate safety" by introducing the involvement of society into the process. Other Members thought that it was a misleading concept that allowed a complacent approach to what is a dynamic process. In the end, no consensus could be reached within the WG and it was left out.

- Provisions on *emissions* (noise, vibration, radiation, hazardous substances)

The concepts of *emission value* and *comparative emission value* are defined ; various provisions on estimating and reducing emission hazards are added to both parts of the standard.

- Provisions relating to the mobility and lifting functions

EN 292:1991 was framed in line with the essential requirements of the Machinery Directive adopted in June 1989 for application to fixed machinery not used to carry out lifting operations. The Directive was subsequently amended to include requirements relating to the specific risks created by the fact that some equipment is mobile and others (or the same ones) carry out lifting operations. The revision of EN 292, therefore, had to take this amendment into account.

With this in view, the Special Working Group undertook, in a first step, to specifically add a Part 3 to the revised standard. At a further stage, it appeared that the basic provisions relating to the mobility and lifting functions could be included, without expressly using the words, into the clauses of EN ISO 12100-2 dealing with the three steps : inherently safe design, safeguarding, information for use. Therefore, the drafting of Part 3 was stopped, so that, in 1997-1998, the Special Working Group could successfully adopt this form for ISO 12100.

**From EN 1050: 1996 Safety of machinery – Principles for risk assessment to ISO 14121****Origin and scope of EN 1050**

EN 1050:1996 *Safety of machinery – Principles for risk assessment*, published in the Official Journal of the EU in 1997, is a Type-A standard outlining the principles for a coherent, systematic procedure for risk assessment. It was formulated to elaborate on the information given in EN 292-Part 1, which was limited to basic concepts. Subsequently, ISO adopted it as ISO 14121:1999.

**The revision of EN 1050: a new vade-mecum for risk assessment**

As soon as EN 292 was about to be revised as EN ISO 12100, a number of standard-setters felt the need to align EN 1050 accordingly.

Two elements have played an important role in the revision of EN 1050. They came into play in 2002, during the discussions among machinery safety experts at CEN, ISO and IEC level. On the one hand, some experts suggested exploring the possibility of elaborating a practical guide on machinery risk assessment. On the other hand, a group of experts in ISO and IEC started exerting pressure to improve EN 1050 in the light of the functional safety concepts introduced in the standard IEC 61508:1999 Functional safety of electrical/electronic/ programmable electronic safety-related systems. These experts offered the evidence that Technical Committees in CEN and ISO were developing their “own” checklist when applying EN 1050 during the preparation of Type-C standards. In the experts’ opinion, this could lead to inconsistent interpretation and application of EN 1050.

In 2003, it was decided both at CEN and ISO that the revision of EN 1050 would be done in an ISO/TC WG with CEN / TC 114 keeping a watching brief on the work. The revision started in 2004 within ISO (in the working group WG 5 of the technical committee ISO/TC 199) and should come to an end in 2007 with the publication of a standard (ISO 14121-1) and of a Technical Report (ISO TR 14121-2) replacing the former Annex B and intended to provide guidance and examples to help designers carry out risk assessment.

Today, the status of the draft document is "pending", prior to the launch of the parallel formal vote in ISO and CEN, after a negative pre-formal vote assessment by the Machinery Consultants and a positive assessment by the Consultants on Noise. This means that there is still a possibility that the document will be withdrawn from the Vienna Agreement, with the consequence that ISO and CEN will finalize separate standards on risk assessment.

The ongoing revision of ISO 14121 will inevitably exert an influence on the evolution of EN ISO 12100, a very close link between both actions being desirable.

**From EN 414: 1992 Safety of machinery – Rules for the drafting and presentation of safety standards to CEN Guide 414 / ISO Guide 78 (2004)**

**Scope of EN 414**

EN 414 lays down rules for the presentation of standards requested by CEN/BT in the programme mandated by the EC in support of the Machinery Directive, and supplements the CEN/CENELEC internal regulations for all European standards with specific additional provisions related to the Machinery programme. The two main aspects dealt with in EN 414 are:

- how to work in a CEN group with a view to producing A-/B-/C-type standards (need for standardization, interested parties represented in the working group, method of work);
- how to work out the standard (hazard list, protective measures, verification of the application of the protective measures, information for use, formal wording for some parts of the standard, Annex ZA establishing the relation between the provisions of the standard and the essential safety requirements of the relevant directives).

Some significant risks generated by machinery are dealt with by other directives than the Machinery Directive (e.g. explosive atmospheres). If these are dealt with in the standard, there should be separate Annexes Z for each relevant directive.

**The revision of EN 414: better rules for standard-setters**

EN 414 'Safety of Machinery – Rules for the drafting and presentation of safety standards' came into being at the end of 1988 and was published in 1992, under the direction of CEN/TC 114, notably its working group 4 (WG4). In 1993 a revision process began. In June 1994 a first draft (prEN 414) was circulated within CEN for comments, and discussed at length by the experts following the activity of CEN/TC 114/WG 4. A significant change was the introduction of Annex ZA with details on relations with New Approach directives. In 1996, the draft prEN 414 was submitted to a public inquiry, and three years later to a formal vote. This first revision led to EN 414:2000.

The ETUI-REHS followed the process with particular attention, since EN 414 was intended to address essential aspects like the scope of type-C standards, the definition of significant hazards and state of the art, the reference to noise and vibration, among others. A second revision of EN 414 started in 2003, following two CEN/TC 114 resolutions calling for an update of EN 414 to avoid contradictions with CEN/ISO rules, and requesting the secretariat of CEN/TC 114 to investigate the most appropriate method and format for the future of EN 414, e.g. as a CEN Guide. The ETUI-REHS took part in the second revision of EN 414 that culminated in 2004 in the publication of CEN Guide 414 which has become ISO Guide 78.

The innovations introduced in 2006 by the new Machinery Directive make it necessary to update the CEN Guide 414 / ISO Guide 78.

**From EN 954:1996 Safety of machinery – Safety-related parts of control systems to EN ISO 13849-1:2006**

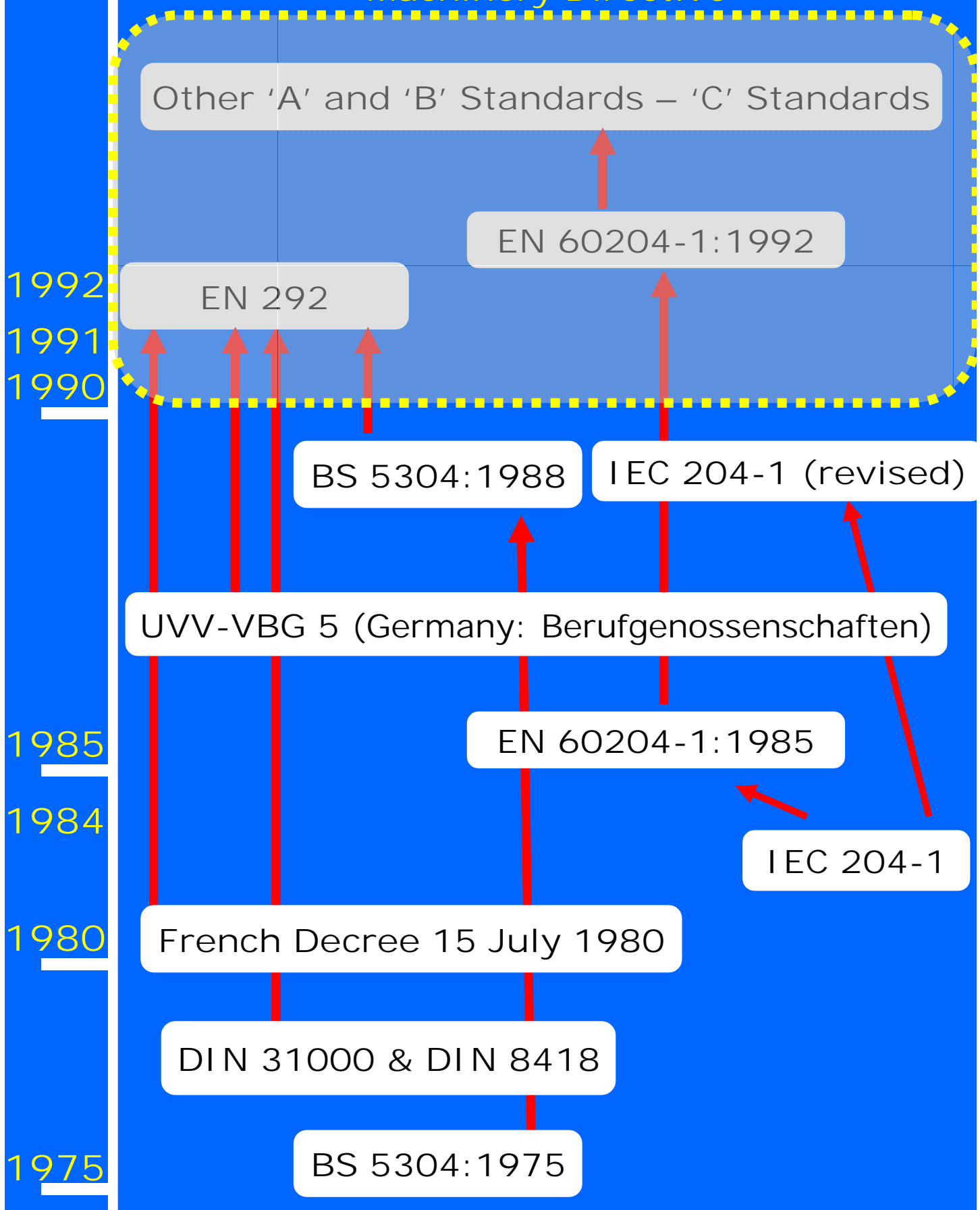
**Scope of EN 954**

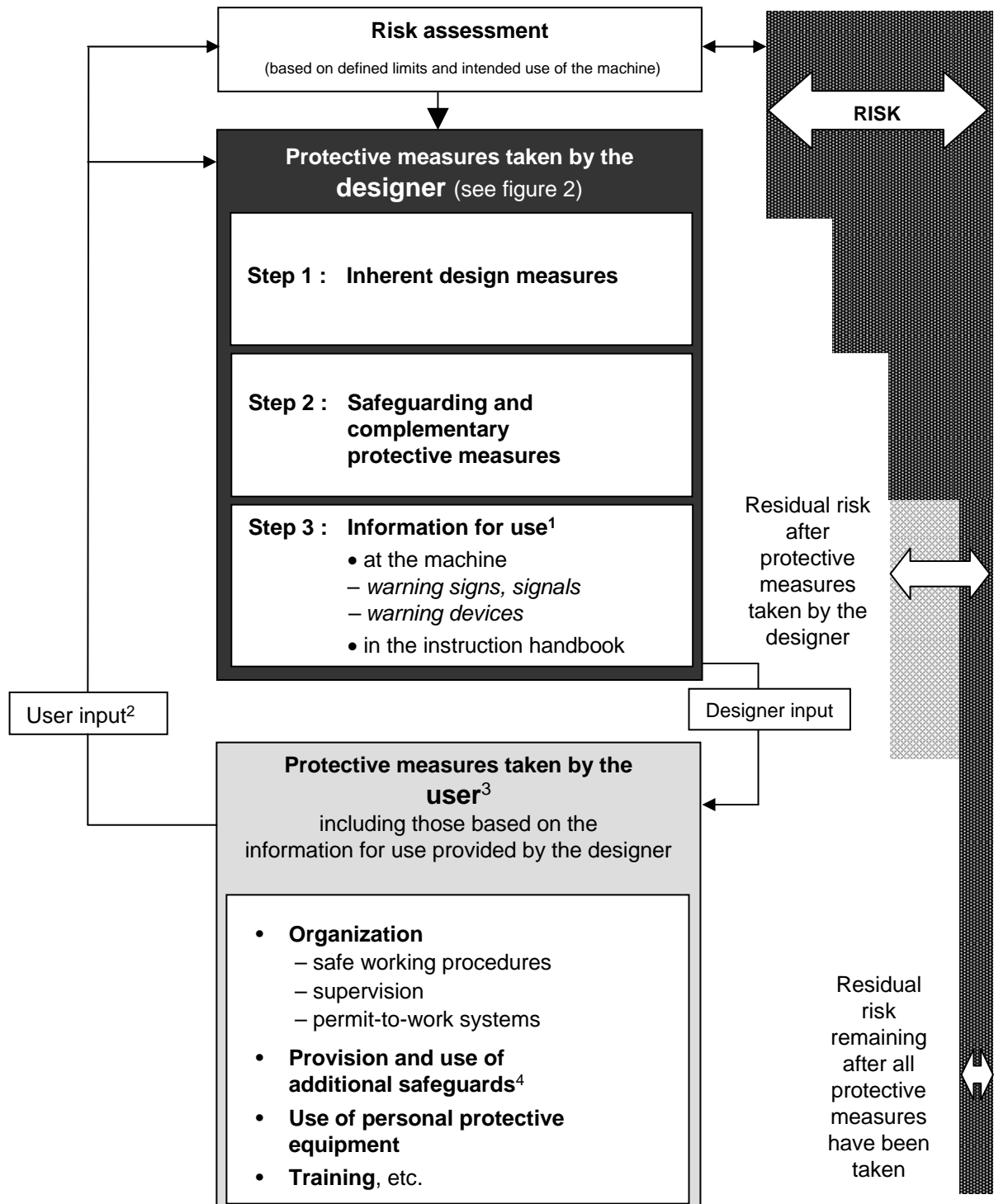
Together with EN 292 and EN 1050, EN 954 forms part of the CEN framework of standards which create a link between type-A and type-C standards, and so fulfils an essential role in the programme of standards supporting the Machinery Directive. This standard addresses the design of safety-related parts of machinery control systems, regardless of the technology used.

**The revision of EN 954: keeping pace with technological progress of control systems**

Soon after the publication of EN 954 in 1996, international experts started exploring its revision to align the standard to the fast-moving evolution of control system technology. While CEN was starting the amendment of EN 954 under the Vienna Agreement, IEC started adapting the requirements of standard IEC 61508:1999 *Functional safety of electrical / electronic / programmable electronic safety-related systems* to the machinery sector. Even if the new IEC 62061 *Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems* was intended to complement the new EN 954 (EN ISO 13849), it was apparent that, sooner or later, the development of both standards would overlap. Today, EN ISO 13849-1:2006, that will soon supersede EN 954-1:1996, covers a wider range of technologies. This raises the question of whether the industry will be ready to understand and integrate the new technical specifications in good time. Once the new standard becomes available, the industry will have three years to make a smooth transition from the old to the new requirements. Secondly, it remains to be seen how standard-setters will revise the risk assessment of the Type-C standards affected by the new standard on safety-related parts of control systems. Finally, the publication of EN ISO 13849-1:2006 calls for a clarification of its interconnections with IEC 62061 *Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems*.

# Standardization in support of the Machinery Directive





<sup>1</sup> Providing proper information for use is part of the designer's contribution to risk reduction, but the protective measures concerned are only effective when implemented by the user.

<sup>2</sup> User input is that information received by the designer from either the user community regarding the intended use of the machine in general or that which is received from a specific user.

<sup>3</sup> There is no hierarchy between the various protective measures taken by the user. These protective measures are outside the scope of this standard.

<sup>4</sup> Those protective measures required due to specific process(es) not envisaged in the intended use of the machine or to specific conditions for installation that cannot be controlled by the designer.