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Globalizing technical standards

Impact and challenges for occupational health and safety

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Impact and challenges for occupational health and safety

Ed. **Theoni Koukoulaki**
and **Stefano Boy**
TUTB researchers

European Trade Union Technical Bureau for Health and Safety

TUTB

SALTSA

Foreword

The TUTB is the European trade union movement's means of giving input into technical standards development. It is an associate member of CEN. The TUTB has repeatedly argued that trade unions are not closely enough involved, and that users generally have too little say in the standard formulation activities that underpin a common technical culture of safety and prevention.

After more than a decade's work in this field, it was time for the TUTB to look again at trade union participation in the standardization process. The hurdles at both national and European level are all-too familiar : under-resourcing (human and financial), gaps in technical knowledge and language skills, no real public commitment to providing union reps with the means to participate. At the same time, we wanted to look beyond these extrinsic obstacles to standards development and look at the intrinsic scope for informing technical standardization with operators' experience and put forward systemic solutions.

To do this, we set up a three-year, three-stranded research programme in partnership with the Swedish SALTSA Programme to :
- revisit trade union participation in the standardization process;
- analyse the impact of globalization of technical health and safety standards;
- develop a participatory approach to work equipment design.

The project outcomes will be published in two stages.

The present publication sets the European standardization process in its changing context where European standards are increasingly being framed at the international level.

The development of standards to fill out the European directives that ensure free movement for work equipment but also affect health and safety is now moving up to a more global setting. At the time when the European Union brought in its New Approach to technical harmonization, standardization was essentially a national exercise. Now, industrial production is almost without exception a European and international activity : in a globalized market with strong growth in international trade, manufacturers see international standards as a key to gain market access and boost trade.

This book sets out to exemplify some aspects of the current debates on how European and international standards as developed in the ISO and IEC can affect the health and safety of Europe's workers.

The other two strands of our research programme will be reported in a second publication in 2003. It will first review 10 years of Swedish trade union participation in both the national and European standardization process, including an overview of the experience of German trade unions, followed by a presentation of the results of an analysis of 36 case studies in employee participation in work equipment design in seven European countries, identifying the criteria for success and proposals for laying the systemic foundations of a participatory approach.

Marc Sapir
Director of the TUTB
December 2002

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Introduction

Nearly 20 years ago, the European Union fundamentally changed the way it harmonized national laws on product safety. These laws covered work equipment (e.g., machinery) or consumer products (e.g., household electrical appliances, toys), as the case may be. The overhaul created a new division of responsibilities between public authorities and the private players linked together within the European standards institutions. This policy shift, known as the New Approach, was greeted with misgivings and criticism from national trade unions and the ETUC alike, who were against a market-driven, restricted and qualified harmonization. After long-running debates in both the Council of Ministers and the European Parliament, directives setting the framework for the free movement of work equipment and placing obligations on designers were adopted jointly with directives laying down employers' obligations and workers' rights of information, consultation and participation at work. The "products" directives proclaim their aim as free movement and improved safety standards, and endorse the principle of social partner participation in the technical standardization process, which had until then gone on out of the public eye.

Once these directives had become law, the European standards institutions set up a publicly-funded programme on work equipment, and opened their doors to the social partners at European level.

The TUTB gives the European trade union movement's input to this work. Time and again it has stressed that social partner involvement is still too limited, and that users generally still have too little say in standardization work, which is the foundation of a common technical culture of safety and prevention.

Since the European Union signed up to the agreement setting up the World Trade Organization in 1994 - especially the annex on technical barriers to trade - the balance struck at European level under the New Approach is inexorably tilting off-beam.

This book illustrates some elements of the current debate on the ways in which European and international standardization as developed by ISO[1] and IEC[2] might affect the health and safety of workers in Europe. At the time the European Union (EU) launched its New Approach to Technical Harmonization, standardization was essentially a national exercise. Today, the product-related activity has almost entirely moved to the European and international level : in a global market with a dramatic increase in world trade, the use of international standards is viewed as having the potential to enhance market access and facilitate trade.

1. International Organization for Standardization.

2. International Electrotechnical Commission.

The new dimension of standardization in supporting the implementation of EU directives and policies on free movement of work equipment and related health and safety matters is today moving towards a more global context. In the framework of the Agreement on Technical Barriers to Trade (TBT Agreement), in particular, the EU has agreed to ensure that standards and technical documents are not used as barriers to international trade. Furthermore, the TBT Agreement states that when developing technical standards and regulations, nations should utilise to the greatest extent possible any and all relevant *international standards* that may exist. They may, however, utilise national standards in areas such as human health and safety, where justifiable.

These obligations are far from being understood in the same way around the world, and questions have been raised over the years both by WTO members themselves as well as by trade unions and other organisations. The EU in particular has voiced its concern to the WTO about how to address the potential interlinkages between the international trading system and the environment, sustainable development, social issues and workers' and consumers' health and safety. Canada's complaint under the TBT agreement against France's asbestos ban exemplified these concerns of the ETUC and EU. The WTO's dismissal of the complaint nevertheless pointed up the need to further develop a dialogue involving the ILO and the WTO on issues relating to trade, labour and social development, as well as the WTO's recognition of trade unions as "amicus briefs". This implies recognition of the right of trade unions and other organizations to put their views and contributions in the dispute settlement procedure set up by the WTO Agreement.

3. As at 1 July 2002, the code had been ratified by 145 standardization bodies in 101 countries.

4. COM (2001) 527 final.

Questions have also been raised in connection with the Code[3] of Good Practice for the preparation, adoption and application of standards attached to the TBT Agreement, about what *international standards* are, which bodies should frame them, and the procedures to be followed. The European Commission report[4] on this pointed out the need to address issues like transparency, balance of interest, impartiality and accountability, as well as health and safety, in the context of the TBT Agreement review. In this context, the main issue for the trade unions is how standards can help preserve the delicate balance between the economic pressures of free trade and the social commitment to protect workers and consumers.

Moving that balance up from a European to a world scale inevitably adds new features and brings new challenges : the relation of standards to legislation, the duties of manufacturers and users, the framework in which standards are prepared, the representation of legitimate user interests and the perception of risk, are among the issues that are raised.

The aim of this publication is to explore how different product-related aspects of workers' health and safety are being addressed in the standardization process when shifting from CEN to ISO. In particular, the principles of the New Approach directives and European standardization procedures arguably face challenges in the new, more globalised context. European development of safety of machinery standards is mainly based on "harmonised standards" that fill out the essential requirements of New Approach directives on machines and other products. Harmonised standards are "mandated" by the European Commission to CEN (and usually also to CENELEC and ETSI). A hierarchy of technical standards has been set up under the European standardization programme, with *A-type standards* laying down basic safety concepts and principles, *B-type standards* on particular safety aspects that can be used across a wide range of machines, and *C-type standards* specifying detailed safety requirements for a particular type of machine or group of machines.

The interplay between regional and international standardization bodies is currently regulated by the Vienna[5] and Dresden Agreements on technical co-operation between CEN and ISO, and CENELEC and IEC, respectively, which are intended to facilitate and ease the workload of standardization, both in terms of time and cost, and avoid duplication of effort.

5. http://www.cenorm.be/BOSS/pp000.htm.

The Vienna Agreement, in particular, allows CEN to decide, on a case-by-case basis and subject to precise conditions, to transfer the framing of European standards to ISO. CEN can adopt ISO projects as European standards, with or without technical changes. CEN may also submit projects to ISO for inclusion in the work programme of an appropriate ISO Technical Committee; upon approval as an international standard, the project could then be adopted as a CEN standard. The new Guideline for the implementation of the Vienna Agreement (adopted on 20-9-2001), further expands the role of non European representatives in the relevant CEN committees and gives them the right to submit comments at the CEN public enquiry stage. It cannot yet be told what impact this new guideline will have.

This publication presents a collection of contributions on representative standards that were developed under the previous guideline implementing the Vienna Agreement. They span a full range of technical standards (A, B and C types) dealing with different aspects of health and safety, and illustrate the challenges of the interplay between CEN and ISO. They are also linked to an objective to which TUTB attaches great importance - that of developing participatory design of work equipment and the collection of data from its actual use to improve the quality of design standards.

The contributions have been written by scientists and experts that were involved in the ISO - CEN standardization process, either as chairs or members of the relevant technical groups. The first set of papers deals with general safety principles and technical aspects of machine safety, including risk assessment, computer control systems and information for use. Two further contributions look at the ISO mental workload series of standards recently adopted as European standards and a related Guidance document published by the Commission. Although these EN standards were not drafted under a New Approach directive mandate, being currently a normative reference in the amended version of EN 614-1[6] on ergonomic principles, they could become part of a mandated standard under the Machinery Directive. Also, mental load is a highly significant concept in designing human-machine interfaces. Even from the limited sample of standards and issues presented here, a number of questions and issues can be identified.

6. PrEN 614-1 Safety of machinery - Ergonomic design principles - Part 1: Terminology and general principles, 2002, *currently at first enquiry stage.*

When technical work moved from a CEN to an ISO technical committee, different and sometimes conflicting interpretations of safety concepts appear. These often stem from differences in the legislative environment and social protection policy in Europe compared to other countries around the world. This uneasy shift from CEN/CENELEC to ISO/IEC is also illustrated by issues like the obligations of manufacturers and users, the integration of new technologies and the meaning of the state of the art, and finally, the relationship between standards and legislation.

The contributions on mental workload illustrate further problems with the transfer of technical documents from ISO to CEN. In the voting process, these ISO standards faced more difficulties at CEN level from European countries than from the same countries at ISO level[7]. This is largely because mental load and stress are key issues in the work environment and the debate on it in Europe, in spite of the fact that mental load is among the Machinery Directive's essential safety requirements. While the terminology and to some extent the approach in the ISO standard may differ from the European guidance on stress, (at present the only guidance document at European level[8]), the standard requirements can help reduce potential stressors when designing the operator–machine interface and tasks in general.

7. 60% of all ISO committee secretariats are held by ISO members that are also members of CEN, see Mike Smith contribution in : *A decade of international co-operation in standardization: 10 years Vienna agreement,* Vienna ON-2002.

8. Currently, no European New Approach or work environment directives give definitions of stress or mental workload.

The different contributions show the challenge that the requirements of the New Approach directives face in avoiding dilution in an ISO document that will, when adopted, act as a European harmonized standard. It is a very clear and present danger for B-type ergonomic standards whose ISO equivalents are not necessarily restricted to a specific product[9] but also apply to work environment issues which are covered by European directives.

9. As the mandated standards are linked to products like machinery or personal protective equipment.

Finally, the balance of the different interest groups in committees when moving from CEN to ISO is also upset. For European trade unions, in particular, moving the process up to international level significantly adds to the costs and so steadily reduces their involvement.

This book lays no claim to completeness : our intention is to help pick out areas of future concern and opportunities around the "globalisation" of health and safety standards and set a public debate rolling on the ways in which European standards are addressing the public interest, especially workers' demands, and to identify emerging challenges.

Marc Sapir
Director of the TUTB
Stefano Boy
TUTB researcher

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From CEN to ISO and back : opportunities and difficulties for application of the Machinery Directive

By Ian Fraser *

1. The particular legal status of harmonised machinery safety standards

1.1. The impact of the New Approach on machinery safety standards

The Machinery Directive is one of the product safety directives based on the so-called New Approach to harmonisation of technical regulations. The New Approach was conceived as an original mechanism for speeding up the removal of barriers to free movement of goods in order to establish the single market in 1993[1]. The method, which has sometimes been described as "co-regulation", implies a sharing of responsibility for determining the rules between the public authorities and the private interests involved in applying them.

1. See Council Resolution of 7 May 1985, *OJ* of 4 June 1985.

The public authorities, through Directives adopted by the Council of Ministers and the Parliament and implemented in national law, lay down the "essential health and safety requirements", that is to say, in general, the objectives to be achieved, while the detailed technical specifications for attaining these objectives for each product type are dealt with in harmonised European standards adopted by CEN or CENELEC on the basis of consensus between interested parties. According to the Machinery Directive, application of the essential requirements must take into consideration both a risk assessment for the type of machine concerned and the "state of the art"[2]. Under the New Approach, the job of identifying the state of the art for a particular

2. Directive 98/37/EC of the European Parliament and of the Council of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (formerly 89/392/EEC as amended), Annex I, Preliminary observations 1 and 2.

* When he wrote this paper, Ian Fraser was a research officer in the Department for working conditions and occupational risk prevention at the French Ministry of Labour. He is now working at the DG Enterprise of the European Commission in the field of lifts and machinery. The views expressed are his own.

aspect of machinery safety or for a particular type of machine is assigned to technical standards.

Application of the standards remains voluntary; however, products manufactured according to harmonised standards are presumed to be in compliance with the essential health and safety requirements. Even if a manufacturer chooses not to apply the specifications of the relevant harmonised standard, he cannot ignore it. The manufacturer can choose alternative technical solutions, but, since he must take account of the state of the art, he must achieve a level of safety at least equivalent to that represented by the harmonised standard's specifications.

The New Approach has now been applied in the field of machinery for about ten years : the Machinery Directive was adopted in 1989 and has been applicable since 1993, with transitional periods extending from 1995 to 1997 according to the type of machinery. One of the most important effects has been the development of a major corpus of European standards for machinery safety. These include horizontal standards setting out the basic methodology for designing safe machines or for carrying out risk assessment (known as type-A standards), horizontal standards dealing with particular aspects of machinery safety (known as type-B standards) and standards providing specifications for particular types of machinery (known as type-C standards).

The unprecedented programme of standardisation launched in support of the Machinery Directive has taken rather longer than expected to carry out; however, the initial objectives will soon be realised : the CEN has already adopted over 400 machinery safety standards and another 200 or so standards will be adopted in the next few years. It is clear that recourse to the New Approach in the field of machinery safety in Europe has proved a major stimulus to the development of machinery safety standards.

1.2. Tension between regulations and standards

However, the link established by the New Approach between the mandatory legal regulations laid down by public authorities and voluntary technical standards adopted by bodies of experts representing private professional interests has, not surprisingly, given rise to tensions.

On the one hand, the public authorities who are used to establishing, interpreting and enforcing regulations (government agencies, labour and product safety inspectors, judges), have had some difficulty accepting the idea that the practical interpretation of the law is now partly entrusted to private interests.

Indeed, application of this type of "co-regulation" raises several objective problems, not the least of which is availability of standards. Laws and regulations are public texts, which everyone is supposed to know, whereas standards are covered by copyright and available only for sale. Since the translation of standards is left to national standards bodies, in smaller countries where these bodies have limited resources, standards are often not available in the national language and have to be ordered from standards bodies in other countries.

On the other hand, it has also been difficult for many standards experts to accept that the special role assigned to harmonised standards under the New Approach carries with it new responsibilities and constraints. Standardisation is based on consensus between interested parties, and the natural tendency of standards development groups is to state what everybody agrees on and to avoid subjects on which there is strong disagreement. However, when working on draft harmonised standards, the standardisation organisation works to a formal remit based on compliance with the mandatory essential health and safety requirements. If application of a product standard is to confer a presumption of conformity with these requirements, the standard must clearly satisfy all the requirements applicable to the product concerned, taking into account the risk assessment and the state of the art.

The ultimate check enshrined in the legal framework for harmonised standards supporting the Machinery Directive is the procedure whereby Member States and the Commission are able to contest harmonised standards whose requirements do not entirely satisfy the essential health and safety requirements[3].

3. Directive 98/37/EC, Article 6.

Although this power given to Member States and the Commission has been used sparingly up till now, the fact that several Member States have already had recourse to the procedure has alerted the standards bodies to the need to check the compliance of standards with essential requirements before their final adoption. CEN and CENELEC's appointment of consultants tasked with vetting draft standards for compliance has had a positive effect on the quality of harmonised standards.

In order to avoid recourse to the formal objection procedure, the public authorities of several Member States attempt to monitor progress of draft harmonised standards and make any objections known to the working groups before the standard is finally adopted. However, as more and more harmonised standards are applied by machinery manufacturers, use of the safeguard procedure will tend to become not just a possibility but a necessity for public authorities in charge of machinery safety when deficiencies in the standards are revealed. This can be illustrated by a recent fatal work accident in France involving an industrial forklift truck.

A worker crossing a factory yard was knocked down and killed by a forklift truck. The driver of the truck had not seen him. The enquiry showed that the visibility from the driving position of this truck was insufficient. Proceedings were taken out against the manufacturer of the truck for non-compliance with the Directive's essential requirement concerning visibility from the driving position. In his defence, the truck manufacturer claimed that the truck was designed according to the relevant harmonised standard and produced a test report certifying that visibility from the driving position complied with the requirement of the standard.

In such a case, if the manufacturer has applied the standard's requirement correctly, the enforcement authorities must use their power to contest the deficient provision. Failure to do so would render the authorities themselves liable for negligence. This legal context provides a strong incentive to both authorities and standards bodies to remedy deficiencies revealed by practical application of harmonised standards.

2. The move from CEN to ISO... and back

2.1. A new phase for machinery safety standards

A new phase for harmonised machinery safety standards is opening with the revision of the first generation of standards adopted in support of the Machinery Directive. The five-yearly revision process provides an opportunity to improve existing standards, taking into account technical progress, the lessons learnt by the standards makers over the past ten years and, above all, experience in using machinery designed according to the existing standards.

For several groups of standards, it is planned that the revision of the European harmonised standard should coincide with the adoption of a single standard at European (CEN) and international (ISO) level, using the procedures for co-operation agreed between ISO and CEN. Since, under the impetus of the New Approach and the Machinery Directive, European standardisation in the field of machinery safety has gained a considerable advance, the method being proposed is for ISO to use the existing European standard as a first draft for discussion within ISO. When the draft ISO standard is ready, it will be simultaneously proposed as a revised harmonised European standard. The aim is for ISO and CEN to have an identical standard within the space of two to four years.

Important steps to facilitate the process have already been taken. ISO Technical Committee 199, which deals with machinery safety standards, has already adopted several horizontal and methodological standards originating from CEN, including the all-important standard on risk assessment[4]. A joint working group of CEN, CENELEC, ISO and IEC has finished preparation of a draft standard on the basic methodology for machinery safety based on a revision of European standard EN 292, parts 1 and 2, which is up for formal vote at European and international level[5]. This work provides a methodological framework for international machine safety standards consistent with the principles enshrined in the European Machinery Directive.

4. EN 1050:1996 / ISO 14121:1999 Safety of machinery - principles for risk assessment.

5. ISO/DIS 12100-1 and 2 Safety of machinery, basic concepts, general principles for design.

2.2. The advantages of global standards

The adoption of global safety standards for machinery based on European standards undoubtedly has great advantages :

- For European manufacturers operating on the world market, the existence of a recognised global standard reduces the need to design different versions of their products for each national or regional market, thus permitting economies of scale.
- Discussion of standards at an international level can make available wider experience and thus enrich technical input to the drafting process.
- The fact that European standards are often providing the starting point for draft global standards gives European manufacturers a head start.
- For manufacturers from third countries supplying the European market, the availability of a global standard facilitates compliance with European safety regulations.
- For enforcement authorities in Europe, the availability of a global standard should improve the level of compliance of machinery coming into the European market and facilitate dialogue with manufacturers from third countries.
- The availability of high quality global safety standards should have a beneficial effect on the general level of safety of the machinery provided to end users, workers and consumers.

2.3. The difficult passage from CEN to ISO

However the passage of safety standards from CEN to ISO and back is also fraught with difficulties.

2.3.1. A different relationship between regulations and standards

The relationship between ISO standards and national regulations varies considerably from one country to another. In some countries, such as the US, there are no regulations on machinery safety applicable to manufacturers and suppliers of machinery. Nonetheless, standards have considerable legal weight in the US, since they may be invoked by accident victims in claims for compensation against machinery manufacturers. In other countries, national regulations sometimes refer to national or international standards. However nowhere else is there a systematic link between regulations and standards comparable to the European New Approach.

At an international level, there is thus no legal framework laying out the safety objectives to be met by ISO standards. The content of ISO standards is determined exclusively by agreement between interested parties. While proposals are being aired to establish a framework analogous to that of the EU's New Approach within an appropriate international forum, global agreement on such an idea is clearly far from an immediate perspective.

2.3.2. A different relationship between duties of manufacturers and users

It is internationally agreed that safety of machinery requires a combination of protective measures taken by the manufacturer and protective measures taken by the user. The latter include correct installation and maintenance of machinery, periodic inspection, appropriate training of machine operators, use of personal protective equipment and so on[6]. In the European legal context, the duties of machinery users are dealt with by legal provisions contained in the Use of Work Equipment Directive[7]. This lays down *minimum* requirements, which means that EU Member States must include at least equivalent provisions in their national regulations, but remain free to keep or to introduce more stringent provisions if these are judged necessary. The protective measures to be taken by users of machinery are not dealt with in harmonised European standards, since they are deemed to know and apply the national regulations in force in the Member State where the machinery is used. Harmonised machinery safety standards must, however, deal with the information which manufacturers must provide to users to enable them to take the protective measures necessary for safe use of the machinery.

The context for international machinery safety standards is quite different. On a global level, there is no uniform relationship between the legal obligations of machinery manufacturers and the obligations of machinery users. It is therefore considered

6. See EN 292-1:1991, figure 1 and ISO/FDIS 12100-1:2001 Safety of machinery, basic concepts, general principles for design, clause 3.27 and figure 1.

7. Council Directive 89/655/EEC of 30 November 1989 concerning the minimum safety and health requirements for the use of work equipment by workers at work, as amended.

useful, particularly for countries with few national regulations in this field, for international machinery safety standards to deal also with the protective measures to be taken by users.

If an international standard is also to serve in Europe as a harmonised standard in support of the Machinery Directive, it is therefore important that requirements concerning the duties of users be clearly distinguished, preferably by inclusion in a separate standard, for they cannot confer the same presumption of conformity as the design requirements.

2.3.3. Different structures and procedures

The relationship between ISO and its member organisations is different from the relationship between CEN and European standards bodies. CEN members are bound to adopt harmonised CEN standards as national standards and to cancel existing national standards on the same subject, whereas ISO members are free to adopt ISO standards or not : they can continue to develop national standards if they prefer.

Under CEN rules, all CEN member bodies can take part in the public enquiry on draft standards and vote on the adoption of the standard. The vote is weighted to take account of each member country's relative size. In the ISO system, a preponderant role is given to the member bodies taking an active part in the drafting of standards. Since taking part in this work at an international level is very costly and time-consuming, many standards are in fact adopted by a small number of member bodies, mainly from the developed countries.

2.3.4. Representation of user interests

The already considerable difficulty of ensuring that participation in drafting of standards is really representative of all interested parties at European level, is compounded at international level. In practice, international standardisation is, for financial reasons, mainly the affair of representatives of major manufacturers. Needless to say, there is hardly any participation by representatives of user interests, trades unions and consumer groups. The task of following simultaneous debates within the European and international frameworks is so daunting that it is difficult for people who are not full-time "standardisers" to follow the drafting process and understand what is at stake.

Given the very different framework within which ISO standards are drafted, discussed and adopted, there is no guarantee that a draft which starts life as a harmonised European standard and is then submitted to discussion within ISO will still be in compliance with the European mandatory health and safety requirements when it comes back as a draft revised harmonised standard.

To illustrate the issues involved, I shall examine two examples of machinery standards, which are already engaged in the process of transfer from CEN to ISO. I stress that the ISO drafts concerned are still under discussion and may change considerably before being adopted. The following comments are personal views and not the official position of any standardisation body or public authority.

3. The example of standards for industrial lift trucks

3.1. The plan for global truck standards : EN 1726-1 and ISO/WD 3691

The harmonised European standard EN 1726-1 on safety of industrial trucks with a capacity of less than 10 000 kg was developed by CEN Technical Committee (TC) 150 and adopted in May 1999. It has thus already been in force for three years and will be due for revision in two years' time. This standard is one of a series of European standards on industrial trucks that have been taken as the basis of ISO/TC 110's development of a series of international truck standards : ISO 3691, parts 1 to 6. The aim, as discussed earlier, is that ISO standards should be adopted simultaneously as revised European harmonised standards. If all goes as planned, there will be a series of global standards for industrial trucks by 2005.

To examine some of the issues this raises, I shall examine the background to the European trucks standard. I shall then compare the requirements of EN 1726-1 with the current working draft of ISO 3691, part 1, bearing in mind that the scope of the six parts of the ISO drafts do not overlay exactly the scope of the corresponding CEN standards.

3.2. German safeguard action on EN 1726-1

The history of European truck standards is a good illustration of the dynamic interaction between regulatory authorities and standards bodies inherent in the New Approach. The present harmonised European truck standards have their origins in regulations, since they took on board most of the content of the technical annexes of the former Trucks Directive[8]. The CEN standard adopted in 1999 marked no significant progress compared with this Directive which came into force some ten years previously, despite considerable evolution in the performance of industrial trucks over this time.

8. Council Directive 86/663/EEC of 22 December 1986 on the approximation of the laws of the Member States relating to self-propelled industrial trucks.

Before the reference of EN 1726-1 was published in the *Official Journal of the European Communities*[9], the German authorities invoked the safeguard procedure, objecting to the lack of specifications in the standard for driver protection in the event of a tip-over of the truck. When an industrial truck tips over, the accident is often fatal because the driver is thrown off the truck and crushed between elements of the truck and the ground. The German authorities pointed out that effective driver restraint systems were now available and were already being installed on trucks in service, in application of European use of work equipment regulations[10]. The German action was supported by other Member States and by the European Commission.

9. Publication of the reference of a harmonised standard in the *OJ* is the legal act which confers presumption of conformity of its specifications with the essential requirements of the Directive.

10. Council Directive 95/63/EC of 5 December 1995 amending Directive 89/655/EEC concerning the minimum safety and health requirements for the use of work equipment by workers at work, Annex I, point 3.1.5.

The Commission decided to publish the references of the standard in the *OJ* with a note indicating that the standard does not confer a presumption of conformity concerning the risk of injury to the driver in case of tip-over[11]. At the same time, the Commission mandated CEN to amend the standard in order to include specifications for driver protection in case of tip-over and also to improve measures to prevent tip-over occurring[12]. This mandate was a clear message from the regulatory authorities to the standardisers that tip-over accidents are still too frequent and that improved protective measures are needed. CEN is in the

11. Commission Decision 2000/361/EC of 10 May 2000 on publication of the references of standards EN 1459:1999 and EN 1726-1:1999, *OJ* L129/30 of 30 May 2000.

12. Mandate M079, Committee 98/34/EC, Doc 3/2000, 17 February 2000.

course of adopting an amendment on driver restraint systems, but further research is considered necessary before new measures to prevent tip-over can be proposed.

3.3. Vexed issues in the proposed changes in ISO/WD 3691-1

3.3.1. Driver restraint and measures to prevent tip-over

The draft ISO standard already includes a clause on driver restraint[13]. However, it is not clear how CEN/TC 150 intends to deal with the Commission mandate to improve measures to prevent tip-over, since revision of the standard is to be carried out within ISO/TC 110. An ISO working group is not, of course, in any way bound by a mandate from the European Commission, although it is free to take these European concerns into account.

13. ISO/WD 3691-1 Industrial trucks – Safety requirements and verification – Part 1: Self-propelled other than driverless, variable-reach trucks, and burden-carrier trucks, clause 5.7.7.

3.3.2. Coasting of pedestrian-controlled trucks

The ISO draft includes a new provision, introduced at the request of the US delegation, accepting that certain pedestrian-controlled trucks (low lift order picking trucks) be provided with a so-called "coasting" system, enabling the truck to continue to travel at a speed of 6 km per hour when the travel control is released[14]. It is clear that such use of a pedestrian-controlled truck makes it possible to increase productivity during order picking work; however, it creates considerable additional risks both for the operator and for persons close to the truck. It also clearly goes against an essential safety requirement of the Machinery Directive concerning movement of pedestrian-controlled machinery :

14. ISO/WD 3691-1, clause 5.4.2.8.

> "Movement of pedestrian-controlled self-propelled machinery must be possible only through sustained action on the relevant control by the driver[15]."

15. Directive 98/37/EC, Annex I, point 3.3.4.

3.3.3. Use of personal protective equipment instead of integrated safety measures

The draft ISO standard admits the use of a personal fall protection device instead of protective rails to protect the operator on the platform of a stand-on truck against the risk of falling from a height[16]. This is contrary to the principles of safety integration

16. ISO/WD 3691-1, clause 5.7.3.6.

expressed in the Machinery Directive, according to which use of personal protective equipment is reserved for residual risks, that is to say, risks which cannot be dealt with by protective measures integrated on the machine :

> "In selecting the most appropriate methods, the manufacturer must apply the following principles, in the order given :
> - eliminate or reduce risks as far as possible (inherently safe machinery design and construction),
> - take the necessary protection measures in relation to risks that cannot be eliminated,
> - inform the users of the residual risks due to any shortcomings of the protection measures adopted, indicate whether any particular training is required, and specify any need to provide personal protection equipment[17]."

17. Directive 98/37/EC, Annex I, point 1.2.2. (b).

3.3.4. Standardising the use of goods lift trucks for lifting persons

The draft ISO standard has a new clause with requirements for the occasional use of a lift truck with a work platform, or, in other words, the use of a lift truck for lifting persons. The draft clause states that use of a work platform with a lift truck should only be envisaged if there is no other practical option (scaffolds, elevated work platforms, aerial baskets etc.) to perform the needed work[18]. This clause is problematic in the European context.

18. ISO/WD 3691-1, clause 5.14.

Firstly, it is difficult to imagine a situation in which a work platform on a lift truck can carry out work which cannot be done more safely from a purpose-built elevating work platform. Secondly, the proposed specifications of the new draft clause do not meet the essential safety requirements of the Machinery Directive for machinery designed for lifting persons[19].

19. Directive 98/37/EC, Annex I, point 6.

Thirdly, the European Use of Work Equipment Directive as a general rule prohibits equipment designed for lifting goods from being used for lifting persons. Exceptions are dealt with by national regulations[20]. In practice, national regulations on this question vary considerably from one EU country to another. In France, regulations on this question are very restrictive and rule out the use of work platforms on lift trucks[21]. In other EU

20. Directive 95/63/EC amending Directive 89/655/EC, Annex II, point 3.1.2.

21. Article R. 233-13-3 of the French Labour Code.

countries, the practice is authorised under specified conditions. It would therefore be misleading to users of work equipment to include provisions on use of work platforms on lift trucks in a harmonised standard.

4. The example of standards for mobile elevating work platforms

4.1. Delay to EN 280 due to French objections

Development of the European harmonised standard for mobile elevating work platforms (MEWPs) by CEN/TC 98 was long and difficult. On many technical questions, the authors of the standard had no existing data to rely on, and each proposed solution had to be tested by manufacturers and testing houses before being included in the draft. They then had to take account of the new Machinery Directive and its successive amendments, the development of new horizontal machinery safety standards and the continual technical evolution of the MEWPs themselves. The difficulty of the task was compounded by the ambitious decision to deal in a single standard with all the different types of platforms using different technologies and creating different risks.

Final adoption of the standard was further delayed by French objections over the problem of load control. Although the French authorities did not invoke the safeguard procedure, they let it be known that they would lodge a formal objection to the standard if the essential safety requirements of the Machinery Directive on load control were not dealt with in a satisfactory way[22]. The CEN group was aware that the French position would probably be supported by other EU Member States and by the European Commission.

After two years of further arduous discussion to reach a solution on load control acceptable both to the CEN Working Group and the French authorities, the standard EN 280[23] was finally adopted in July 2001.

22. Directive 98/37/EC, Annex I, points 4.2.1.4. and 6.1.3.

23. EN 280:2001 Mobile elevating work platforms - design calculations - stability criteria - construction - safety - examinations and tests.

4.2. The plan for a global standard for MEWPs

Work started in 1998 within ISO/TC 214[24] on an equivalent ISO standard for MEWPs taking the existing draft of EN 280 as a basis for discussion. The ISO Working Group was aware that discussion was still going on in CEN/TC 98 on the question of load control, and they agreed to include the results of that discussion in a later draft.

24. The countries participating in the Committee are Australia, Austria, Canada, China, Czech Republic, Finland, France, Germany, Italy, Japan, Netherlands, Norway, Russian Federation, South Africa, Sweden, United Kingdom, United States (i.e. 10 European and 7 non-European countries). The Secretariat is held by the US.

The ISO draft is now in its fourth version, which includes both the definitive version of the EN 280 clauses on load control and changes reflecting comments from ISO members on the first three versions of the draft. In what follows, I shall address three aspects of the comments and changes made to the draft so far. It should again be stressed that the draft is by no means in its final state.

4.3. Editorial improvements

Not surprisingly, the new non-European readers of the harmonised European standard have already been able to make numerous editorial improvements. Since the ISO discussion is based on the English version of EN 280, the English speaking delegations are able to tighten up the language of a standard originally drafted by non-native English speakers. The addition in the ISO draft of titles for all clauses and sub-clauses makes the standard much easier to use.

However, there is one kind of editorial amendment which is worth a particular mention, since it reflects a recurrent problem whenever CEN standards are transferred to ISO level. The US delegation proposes amendments to any wording than might be construed as placing an absolute obligation on the manufacturer.

American manufacturers and their lawyers insist on avoiding "absolute" language because ISO standards may be quoted by lawyers in American courts to support claims for damages from accident victims. Generally speaking, the amendments of this type proposed by the US increase the precision of the text, but vigilance is needed to ensure that they do not result in dilution of the standard's specifications.

4.4. Doubts about the European approach

It took many years for European experts to agree on a common approach to safety of MEWPs. It is clear that several non-European countries will require time to compare the specifications of EN 280 with existing national standards and regulations on safety of MEWPs and assess the consequences of adopting the European approach. Several countries such as Japan, Canada, Australia and the US are apprehensive of transposing the European approach to the international level. Some non-European delegations think application of the Vienna agreements, which aim to avoid duplication of work between CEN and ISO, have unduly favoured Europe.

Japan, for example, clearly has difficulty with the EN 280 clause on stability calculations and is proposing that separate stability criteria be defined for each main type of MEWP. Several delegations have reservations about detailed technical specifications included in the European standard for components like wire ropes or hydraulic cylinders. They fear these may prove obstacles to technical innovation and prefer to rely on recognised design codes. It may be possible to address these objections by admitting equivalent technical solutions.

4.5. Improvement of certain safety measures

The fourth version of the ISO draft includes several changes to the specifications of EN 280 which, if adopted, should improve levels of safety. Other similar improvements are being proposed by national delegations.

4.5.1. Installation of anchorage points for PPE

Following US comments, the ISO draft includes a requirement to install anchorage points for fall arrest systems on work platforms[25]. Although there is no general agreement on when occupants of MEWPs should use PPE to protect against the residual risk of falling from the platform, it seems reasonable that MEWPs should at least be fitted with correct anchorage points so that PPE may be used when required, thereby avoiding the use of unsafe improvised anchorage points such as the guard rail. This

25. ISO/DIS 16368.4 Mobile elevating work platforms - Design calculations, safety requirements and test methods, clause 5.6.3.

is in line with essential requirement of the Machinery Directive :

> "If the measures referred to in 1.5.15 [risk of falling] are not adequate, carriers must be fitted with a sufficient number of anchorage points for the number of persons using the carrier, strong enough for the attachment of personal protective equipment against the danger of falling[26]."

26. Directive 98/37/EC, Annex I, point 6.3.1.

4.5.2. Reinforced strength requirements for hydraulic hoses

Following an Australian comment, the EN 280 requirement for the bursting strength of hydraulic hoses is made more stringent in the ISO draft : when they are critical components, the bursting strength must be four times the maximum pressure in use instead of three times as in the European standard[27].

27. ISO/DIS 16368.4, clause 5.9.3.

4.5.3. Restriction on safety device overrides

American comments have led to a reformulation of the existing clause permitting the overriding of safety devices in certain conditions, to make it clear that overriding is to be prohibited during operation and only authorised for testing, repairing or maintenance purposes[28].

28. EN 280:2001 / ISO/DIS 16368.4, clause 5.11.6.

4.5.4. Better definition of kerb tests

The so-called kerb tests are important dynamic stability tests which simulate the situations that occur when the wheels of a mobile work platform strike an obstacle or fall into a depression in the ground[29]. The standard's specifications concerning these tests are being re-written to clarify the conditions of execution for the different types of MEWP.

29. EN 280:2001, clause 6.1.4.2.2.2. / ISO/DIS 16368.4, clause 6.1.3.1.2.1.

4.5.5. Improved reliability of hydraulic levelling systems

An important question has been raised by the Swedish delegation concerning the need to improve the reliability of work platform levelling systems which depend on hydraulic cylinders. Failure of hydraulic cylinders leading to loss of levelling of the platform and ejection of operators from the platform is too-frequent a cause of serious or fatal accidents.

4.6. Problematic proposed changes in ISO/DIS 16368.4

Other proposed changes in the draft ISO standard appear to involve the lowering of certain safety requirements included in the European standard, or which would go against the requirements of the Machinery Directive.

4.6.1. Accepting the use of MEWPs as cranes

EN 280 defines a MEWP as a machine intended to place persons, tools and materials to working positions[30]. The European standard precludes the use of a mobile elevating lift platform as a crane, i.e., fitting the work platform with secondary lifting apparatus such as hoists or winches for lifting materials[31]. When the work to be done requires extra materials to be lifted to the work position, this is done using other means such as a mobile crane.

30. EN 280:2001, clause 3.1.

31. EN 280:2001, clause 7.1.1.2. e).

Installing secondary lifting apparatus on the work platform increases the risk of overloading and overturning the MEWP, since it enables the operator to add extra load to the platform at a height, including when the platform is at maximum permissible reach. To avoid this risk it would be necessary for the load and moment control devices on the MEWP to prevent dangerous movements not just of the work platform but also of the secondary lifting apparatus. This would amount to equipping the MEWP with the same safety devices as are required for cranes.

The US and Japanese delegations claim that MEWPs are safely used with secondary lifting apparatus on the platform in their countries. They propose in this case that the rated load of the secondary lifting apparatus be added to the forces taken into account for the stability calculations of the MEWP[32]. However, this measure alone is insufficient to deal with the increased risk of overloading that this mode of operation entails.

32. ISO/DIS 16368.4, clause 5.2.3.5.

4.6.2. Alternatives to guarding of trapping and shearing points on scissors lifts

EN 280 requires that MEWPs equipped with a scissors mechanism for raising the platform should have guards to protect people on the ground near the MEWP against the risks of trapping and shearing of hands or arms in the scissors[33]. This is a straightforward application of an essential safety requirement of the Machinery Directive :

33. EN 280:2001, clause 5.4.4.

> "The moving parts of machinery must be designed, built and laid out to avoid hazards or, where hazards persist, fixed with guards or protective devices in such a way as to prevent all risk of contact which could lead to accidents[34]."

34. Directive 98/37/EC, Annex I, point 1.3.7.

On small platforms on which it is considered that the operator has sufficient visibility of the surroundings, EN 280 allows the guard to be replaced by a system whereby the lowering of the platform is halted and can only be restarted after a time delay and a subsequent control command.

The ISO draft extends this exemption from guarding of the trapping and shearing points to any scissors lift, whatever the size of the platform, although there is an added requirement for a lowering warning system[35]. This change, proposed by the US and defended by several manufacturers and hire companies, is supported by two arguments : first, that there is no record of accidents involving hands or arms trapped in scissors mechanisms; second, that guards are often damaged or dismounted and are costly to repair. Both these arguments are open to criticism. The absence of accident records may be explained by the fact that most existing large scissors lifts are equipped with guards. And the damage to guards is often due to poor design and construction or lack of proper maintenance.

35. ISO/DIS 16368.4, clause 5.4.4.

4.6.3. Relaxing the limits on movements

EN 280 specifies that the speed of movements of the platform must be limited to 0.4 metres per second for the lifting and lowering of the work platform and 0.7 metres per second for the rotation and slewing of the platform at maximum reach. The US delegation considers these limits to be restrictions on productivity which are not justified by safety reasons. The present ISO draft admits speeds of double the above values, provided that acceleration and deceleration do not exceed 0.25g measured at the work platform[36].

36. EN 280:2001 / ISO/DIS 16368.4, clause 5.4.6.

However both speed and acceleration of the movement of the work platform are risk factors. High acceleration or braking of movement, even at low speeds, may cause an operator to be ejected from the work platform. Higher speeds increase the risk of collision of the platform with surrounding obstacles, which is a major cause of damage to MEWPs and undoubtedly contributes to serious and fatal accidents. EN 280 included only a limit on the speed of movements of the platform because speed is easier to measure and control. The idea of including a restriction on acceleration of the platform is interesting, but it does not justify the raising of limits on the speed of movements of the platform.

4.6.4. Accepting automatic operation of the work platform

In response to comments from Japan, the ISO draft includes a new clause permitting automatic operation when the controls are released, providing "appropriate safety measures are employed". An example of such a safety measure is a warning device to the operator that the machine is "under operation"[37]. This new clause goes against the essential safety requirements of the Machinery Directive relating to hazards due to the mobility of machinery :

37. ISO/DIS 16368.4, clause 5.7.10.

> "Where their operation can lead to hazards, notably dangerous movements, the machinery's controls, except those with pre-set positions, must return to the neutral position as soon as they are released by the operator."

to the requirements relating to the hazards due to lifting operations :

> "The devices controlling movements of the machinery or its equipment must return to their neutral position as soon as they are released by the operator. However, for partial or complete movements in which there is no risk of the load or the machinery colliding, the said devices may be replaced by controls authorising automatic stops at pre-selected levels without holding a hold-to-run control device."

and to requirements relating to the hazards due to the lifting and moving of persons :

> "The controls for these movements must be of the maintained command type, except in the case of machinery serving specific levels[38]."

38. Directive 98/37/EC, Annex I, points 3.3.1., 4.2.1.3. and 6.2.1.

EN 280 is in line with the Machinery Directive on this point :

> "MEWPs shall be provided with controls such that all movements of the MEWP can only take place while the controls are being actuated. The controls, when released, shall automatically return to the neutral position."

MEWPs are not machines serving specific levels and their controls do not have pre-set positions. All movements of the work platform are potentially dangerous if the operator does not have permanent control. The only interest of allowing automatic operation is to free the operator to do other work during movements of the work platform, and this is dangerous, even with a warning device that the MEWP is in operation.

4.6.5. The status of requirements on information for use

In the ISO draft, only the chapter headings of the EN 280 instruction handbook clause have been retained in the standard itself. The detailed specifications for the content of the instructions for use are relocated to an informative annex[39]. This means that these specifications are not requirements of the standard but simply constitute advice to manufacturers.

39. EN 280:2001, clause 7.1. / ISO/DIS 16368.4, Annex F.

For the Machinery Directive, instructions for use are an integral part of the protective measures to be taken by the manufacturer and must therefore be dealt with in harmonised standards[40]. They constitute a key element of the so-called three-step method described in the fundamental methodological standard on design of safe machinery EN 292, a revised version of which is in the process of being adopted as an international standard[41].

40. Directive 98/37/EC, Annex I, points 1.7.5., 3.6.3. and 4.4.2.

41. ISO/DIS 12100 Part 1, clause 5.4. and Part 2, clause 5.5. (see the article by Jean-Paul Lacore p. 39).

In the European standard describing the rules for drafting machinery safety standards, the inclusion of a clause specifying the content of the instructions for use is described as obligatory[42]. There is no reason why the detailed requirements concerning information for use to be provided by the manufacturer

42. EN 414:1992 Safety of machinery - rules for the drafting and presentation of safety standards, clause 6.10.1.

should not be dealt with in an annex, provided it has prescriptive status, that is to say its contents have the status of full requirements of the standard.

5. Conclusion

5.1. The problematic future of the New Approach

Preparing harmonised European machinery safety standards has required considerable give and take between representatives of the different interest groups and national traditions involved. However, the level of the acceptable compromise is determined, in the European legal context, by respect for the mandatory essential health and safety requirements of the Machinery Directive.

It is clear that preparation of an international machinery safety standard requires similar give and take between national positions from the different continents. Although European standardisation has gained an advance on international standardisation in many fields of machinery safety under the impetus of the New Approach, it would be a big mistake for European machinery safety experts to adopt a systematic “European is best” attitude.

European safety experts should approach the transfer of standards from CEN to ISO with an open mind. Given the advantages of having a global standard, we should strive within ISO to reach agreement on a standard that is both internationally acceptable and in line with the essential requirements laid down by European regulations. This will obviously involve taking into account the different approaches to design and use of machinery existing in different parts of the world. That such agreement is possible has already been shown by progress on global methodological machinery standards.

On the other hand, as examination of some of the problems raised by the transfer to ISO of CEN standards for industrial trucks and MEWPs has shown, the compromises required to reach a new international consensus may lead to the lowering of safety levels or the inclusion in the international standards of specifications contrary to the requirements of the Machinery Directive.

We have seen that within the European New Approach system, there are mechanisms for ensuring that safety standards are in conformity with the essential requirements. Draft standards are vetted for conformity by expert consultants. The public authorities can introduce a formal objection to a non-compliant standard. The European standards bodies increasingly take these constraints into account when preparing harmonised standards. None of these mechanisms exist at the international level.

Similarly, input from end-users, consumer bodies and trades unions, prevention bodies and the public authorities is much more difficult to mobilise at the international level where, to a large extent, global companies call the tune. What should be the attitude of those striving to improve the level of machinery safety in Europe when an unsatisfactory ISO standard is proposed as a draft revised CEN standard?

5.2. The possible answers

5.2.1. Has the New Approach been overtaken ?

One idea is to consider that, within the increasingly global market, the European Machinery Directive must be superseded, and international agreement within ISO should take precedence over "regional" European health and safety regulations. Naturally, Americans, Japanese or Australians will be inclined to take this view. But it also has strong support among representatives of European industry, particularly from manufacturers operating on the world market.

However, I think this answer is, to say the least, premature. Application of the Machinery Directive in Europe has undoubtedly helped to raise the level of safety integration in machinery. But some important essential health and safety requirements are only just beginning to be applied (requirements concerning reduction of emissions of noise, vibrations and harmful substances, for instance). Indeed one of the objectives of the current work on revision of the Machinery Directive is to improve the practical application of the essential requirements. In this context, it would be very rash to abandon a legal framework which has proved its worth, until there is a credible prospect of an alternative system at the international level.

5.2.2. "Regional exception" clauses ?

A second idea is that the points on which the new ISO standards clash with certain requirements of the Machinery Directive may be dealt with as "national" or "regional" exceptions in the ISO standards.

For example in ISO/DIS 16368.4 on MEWPs, the following note is included in the clause on safety requirements :

> "The requirements of this Standard shall apply except where national or local regulations are more stringent[43]."

43. ISO/DIS 16368.4, clause 5.1.

This type of warning to manufacturers may be necessary in an ISO standard, since there is no general relationship at the international level between standards and national regulations. However, inclusion of such a warning cannot enable such a standard to play the role of a harmonised European standard conferring a presumption of conformity with the Machinery Directive. The assurance that this presumption gives to manufacturers and users that correct application of the harmonised standard is a sure way of ensuring conformity with the regulatory requirements would be completely lost if the manufacturer had to check each specification in the standard to see whether the requirements of the European regulations are more stringent or not.

5.2.3. Selective acceptance of ISO standards

I am forced to the conclusion that, despite the undoubted advantage of adopting global standards, we must be particularly vigilant when draft standards coming from the ISO are not in line with the requirements of the Machinery Directive. The objective must be to win over our international partners but if, on a given subject, the result of the international consensus is not satisfactory in regard to the principles of safety integration enshrined in the European Directive, then distinct harmonised standards must be kept for Europe.

When ISO standards or draft ISO standards are submitted to enquiry and formal vote as EN standards in support of the European product safety directives, the European standards bodies must be prepared to insist that the standard should be in line with the essential health and safety requirements. In cases where consensus on conformity with the essential requirements proves impossible to reach, the public authorities in the Member States and the European Commission must be prepared to use the formal objection procedure, even if the draft submitted to the CEN adoption procedures has already been adopted by ISO.

Various outcomes can be envisaged. The ISO standard and the EN standard dealing with the same subject could differ with respect to certain clauses or technical specifications. Alternatively, the European Commission might decide to accompany publication of the common standard's references in the *OJ* with an appropriate warning that certain clauses or specifications of the standard do not confer a presumption of conformity with the European Directive.

From EN 292 to EN ISO 12100 : developments in safe machinery design principles from 1985 to 2002

By Jean-Paul Lacore *

1. Background

Set up in June 1985 in the wake of the *New Approach to technical harmonization and standardization*[1], CEN Technical Committee 114 "Safety of Machinery" set straight to work on framing a "catch-all" standard (all machinery, all hazards that they are likely to generate) as a common basis for all the standards intended to assist machinery designers in applying the essential safety requirements (ESRs) laid down in the Machinery Directive[2], work on which had begun at almost the same time and which was adopted in June 1989. That standard (EN 292[3]) was adopted in November 1991.

1. Launched by the resolution of 7 May 1985.

2. Both the "horizontal" standards (applicable to all machinery) - of which there are now a good hundred - and the "vertical" standards (each applicable to a category of machinery) - of which there are now six hundred-plus.

3. EN 292:1991 Safety of machinery - Basic concepts, general principles for design - Part 1: basic terminology, methodology - Part 2 : technical principles and specifications.

The simultaneous framing of standard and Directive greatly added to the consistency between the Directive's ESRs and the fundamental principles laid down in EN 292. This is because many national authorities' representatives were involved both in framing the directive and the successive draft standards. That helped create a clear shared understanding of basic concepts, especially that of *safety integration*.

2. The concept of safety integration

A designer of machinery who takes every possible step to ensure that to work safely, all a user need do is to stay within the limits of normal use, is applying safety integration.

* Engineer, former chargé de mission for standardization at INRS *(Institut national de recherche et de sécurité)*, Paris. Jean-Paul Lacore has been deeply involved in the activity of CEN/TC 114 "Safety of Machinery" since 1985.

This might seem so obvious as not to be worth mentioning. But it has not always been that way. Where mechanical hazards, at least, are concerned, early-to-mid-20th century machinery catalogue pictures show that users still had to add on many safety devices so as not to expose machinery operators to immense risk. Arguably, machinery operators' employers and trade union representatives, backed up by safety inspectors[4] and armed with work accident and work-related illness figures, were able to step up the pressure on manufacturers to design safety into their machinery. But, if the French experience is anything to go by[5], it was not until the latter half of the century that a sufficient head of pressure built up to push the idea of safety integration effectively, and eventually win legislative recognition and backing for it. In France, this came through the decrees (regulations) of 15 July 1980, enacted under a 1976 Act, laying down the design integrated safety obligations of machinery designers and manufacturers.

4. Labour inspectors and prevention agency staff.

5. If memory serves, J.-M. Cavé, one of the first presidents of the INRS, was closely associated with a major drive to promote safety integration in the very early 70s.

It was clearly an idea whose time had also come in the other European countries, since the partners engaged in framing the Machinery Directive apparently had no difficulty laying down the rules of sound safety integration when framing it. Likewise, the members of the CEN Technical Committee 114 Working Group had excellent benchmark documents – plus properly briefed experts – from a wide range of sources across Europe to work out the initial draft of EN 292 in 1985.

3. The European approach to safe machinery design

3.1. Principles and methods

At the advent of the European single market on 1 January 1992[6], notwithstanding that the Directive had still not been turned into law in some EU member countries, and that many of the EN 292 "satellite" standards were still at various stages of drafting, Europe had a body of regulations and standards based on sound, and, for the most part, tried and tested design principles and methods :

6. Interestingly, the number of the basic standard (292) was chosen as a reference in English to the objective set in the programme: "to ninety two".

a. the *safety integration* principle (see 2, above), enshrined by the recently-adopted official rules;

b. an *iterative method* (by successive "loops") *of risk reduction at the design stage*; in this method, design-integrated safety measures are applied at each "loop" as the result of an initial assessment of the risk[7], and their effect is assessed not just by reference to the reduction of risk achieved, but also by reference to considerations such as not generating new hazards, whether the machine retains its ability to perform its function, whether the operator's and other parties[8] working conditions are unimpaired (see 4.3);

c. *the "3-step method"*, by which the designer will make the best possible use of, successively, *inherent design* measures, then *safeguarding* measures, and finally *information for use*.

7. Standardized in 1995 by EN 1050, the early beginnings of which were already in EN 292:1991.

8. The concept of adequate risk reduction spelled out in Figure 2 of EN 292-1:1991 and point 5.5 of draft EN ISO 12100-1.

3.2. The complementary roles of designer and user

In both the 1991 and revised version (draft EN ISO 12100-1[9]) which looks set to be adopted at the beginning of 2003, EN 292 gives a schematic representation of the complementary roles of the designer and user. It briefly mentions the preventive measures to be applied by the user, noting that these measures fall outside its scope. A comparison of the schematic representation in Figure 1 (p.42) with its counterpart in the revised version (see Figure 2, p. 49) is instructive.

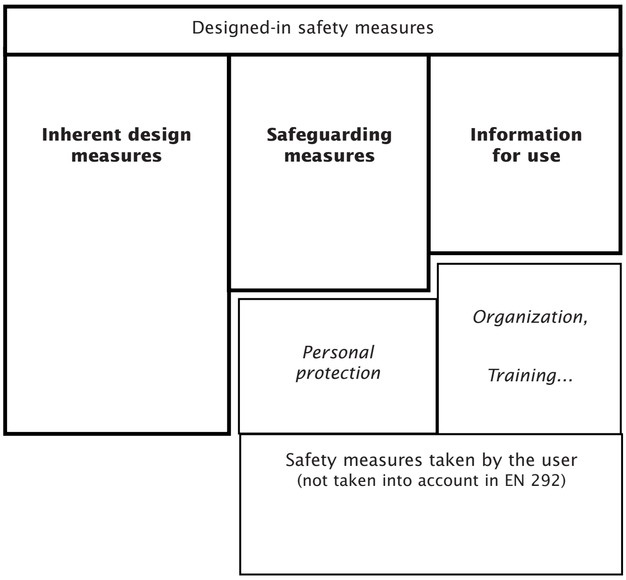
9. We refer throughout this paper to the text prEN ISO/FDIS 12100-1: 2001 Safety of machinery - Basic concepts, general principles for design - Part 1: Basic terminology, methodology.

The philosophy which has underpinned the European regulations and standards on safe machinery design for more than a decade is based on the tried and tested principles summarized below.

- Safety must be integrated to the greatest extent possible at the design stage, i.e., the designer must eliminate or reduce as far as possible the risk resulting from every hazard generated by the machine.
- The drawing up of *information for use* is an inherent part of machinery design (the third and final step of the method described in 3.1.c).
- Where a risk cannot be removed outright – by eliminating the hazard that generates it or completely eliminating the possibility of exposure to that hazard (*inherent design measures*) –, the

protective measures required must be chosen bearing in mind that safeguarding measures designed with the machine as a whole and applied when it is manufactured should always be preferred to individual protective measures.

Figure 1 **Respective tasks of the designer and user in EN 292:1991**



This means that the designer cannot replace a technically feasible safety integration measure with a preventive measure which is to be taken by the user and is described as such in the information for use. That rules out, in particular, any "agreed" sharing of responsibilities for the protection of persons between designer and user (e.g., not fitting a machine with a protective device when it could be fitted, and recommending in the information for use that personal protective equipment be worn).

3.3. Risk assessment

It is natural for machinery designers faced with a safety issue to wonder how it has been dealt with in similar cases, and simply borrow – or adapt – what worked before. While it does not necessarily produce bad solutions, this approach can mean that more innovative, effective, and possibly cheaper solutions are overlooked. The classic case is where a safeguarding measure is applied instead of a “neater” (i.e., at least as effective and possibly less costly) inherent design solution.

The method laid down by EN 292 (and further developed by EN 1050:1996 *Safety of machinery - Risk assessment*) requires the designer to carry out the following sequence of activities :

a. systematically identify, using a detailed check-list, all the hazards that the machinery concerned may generate in all the conditions of use;
b. estimate the related risk as objectively as possible;
c. assess the degree of risk reduction necessary, in circumstances where the considered hazard cannot be eliminated.

This method is just good common sense, and taken together with the check-list of hazards[10], eases the designer’s task and minimizes the risk of omissions. Thankfully, it is to be included in draft EN ISO 12100-1, but the reluctance to espouse it revealed by surveys in the United States is proof positive of how differences between legal systems in different parts of the world can create a major barrier to the internationalization of particular regional standards.

10. A detailed version of which is given in EN 1050.

The legal reasons advanced in some quarters in America for not including a list of hazards that may be generated by a machine in the standard relating to it are surprising, not to say mystifying. If – the argument goes – a manufacturer were to be sued for harm caused by a machine, having such a list would put him more “at risk” than if the standard were less specific about the hazards it is designed to protect people from !

3.4. Reflecting the state of the art and moving it on : two consistent aims

There is a consensus that a good standard must reflect the state of the art[11] at the time it enters into force. By not making the standards compulsory, the European New Approach – in theory, at least – ensured that their provisions do not hold back technical progress. But it is reasonable to expect more of a safety standard : every revision should actually bring about progress in the technology it deals with.

11. There is widespread agreement that the point-in-time *state of the art* is not what can best be done at that time regardless of cost and the number of products achieved, but the most advanced techniques put into practical use which address a defined functional and economic need.

Advances in industrial technology may lead designers to devise solutions which they do not initially realise, if implemented without specific protective measures, will actually endanger machine users. That situation arose in the early days of drafting EN 292 with the use of "control guards" – a technology whereby, following a first machine cycle initiated (in accordance with one of the Machinery Directive's ESRs) by the voluntary actuation of a specifically designed start-up device, the closing of a guard associated with an interlocking device will by itself initiate the start-up of each subsequent cycle, contrary to the requirement concerned[12]. Severe – sometimes fatal – accidents have focused attention on the risk associated with this technology.

12. There may in some cases be good ergonomic grounds for a productivity-driven (cutting "down time" between production cycles) start-up by the closing of a guard or the uncovering of a non-material barrier.

The working group of the time, and inquiries on succeeding drafts, were divided by two opposing agendas :

- make no reference to the technique in the standard because it infringed an essential requirement;
- note that it was already in widespread use – sometimes disastrously so, due to ignorance of its inherent risks – and set strict compliance criteria in the standard to reduce the risk.

The latter view eventually prevailed. But a technique very akin to the use of control guards had gone unremarked in EN 292 : the use of sensing devices (non-material barriers)[13] for the same purpose. In the 70s and early 80s, very severe or fatal accidents had occurred which, especially in France, had led to regulations banning the practice. In United States, a heated debate had raged at the same time on the same practice between press manufacturers,

13. The probable main reason for this "deliberate omission" was that fifteen years ago, non-material barrier technology was considered insufficiently proven for such an application.

users and safety inspectors. That failing will be remedied by draft EN ISO 12100-2, which includes *additional requirements for active opto-electronic protective devices when used for cycle initiation*.

I would not presume to pronounce on the validity or effectiveness of provisions agreed by consensus between the parties concerned – manufacturers, users and safety inspectors – after fifteen of years of discussions. That is a matter for close and consistent, long-term observation of the performance of standards-compliant machinery and intervening fine-tuning reflected by the revised standards. The evidence may point to a "win-win" situation, but that is still no reason for jettisoning the principle that the *start-up* and *prevention of unintended start-up* functions should be achieved by separate devices. However advanced the technology, that will remain a fundamental principle to be assimilated, which can ill-afford to be flouted save in very exceptional, fully justified, cases and then only subject to compensatory measures agreed by consensus between the interested parties.

As has been seen, the European approach to safe machinery design is an ongoing process, based mainly on a constant challenging of the solutions adopted[14]. Hopefully, the standards development process will be likewise. This dynamic approach to standardization is what will help the benchmark documents keep pace with technological and social development, and even, by reflecting the best advances already proven by practical applications, act as a real driving force of it.

3.5. How is the system working in 2002 ?

The principles and methods discussed above seem now to have found general acceptance in Europe[15]. But it is reasonable to wonder how many of those affected have really awakened to and taken them on board. The complex and cumbersome body of rules, regulations and standards that contain them are not readily accessible. Which is why some countries have taken steps to see that the teaching of machinery design is heavily based on the European standards[16]. Results to date have been encouraging, though it is cause for regret that the European Commission has

14. Both EN 292:1991 and its revised version (draft EN ISO 12100-1) contain the following statement : "A machine which is acceptable at a particular time may no longer be acceptable when technological development allows... the design of an equivalent machine with lower (residual) risk".

15. Although the author of this article has heard the view expressed that "too much safety integration takes away machinery operators' sense of responsibility / saps their alertness".

16. The introduction to both EN 292:1991 and its revised version (draft EN ISO 12100-1) states : "It is recommended that this standard be incorporated in training courses and manuals to convey basic terminology and general design methods to designers".

not so far supported this approach. But there is still time for it to do so !

Once the New Approach was launched in 1985, a large number of standards had to be framed at very short notice. The working groups naturally drew heavily on the knowledge base developed by manufacturers and safety inspectors over decades, to reasonably good effect. But it would be a grievous mistake if out of force of habit, future working groups when revising standards in particular, failed also to draw on the rich store of knowledge that machinery users have gained through practical experience. To put it in more positive terms, it would be good if machinery users – including trade unions and consumer groups – were better represented in the working groups than they have been in the past.

4. The revision of EN 292 : from the European to the world arena

4.1. Background and circumstances of the revision

Around 1990, inspired in particular by the successful shift in framing a textile machinery standard from the European to the international level, ISO became interested in the undertaking launched in 1985 to give the European Union a coherent set of horizontal standards on safety integration in machinery design. In November 1991, therefore, ISO Technical Committee 199 "Safety of Machinery" was set up as the international mirror of CEN Technical Committee 114. ISO/TC 199's main task was to submit the standards and draft standards framed by CEN/TC 114 to the international community with a view to turning them into international standards. Barely was EN 292 on the books when ISO made a technical report on it – ISO/TR 12100 – to be put out to the international consultations required to turn it into an international standard.

Without delving into the details of the subsequent history, it is both instructive and essential to note that when CEN and ISO decided to mount a joint revision of EN 292 under the Vienna

Agreement, the task was handed to a CEN Technical Committee 114 Working Group consisting of experts appointed by the respective member committees of CEN, CENELEC, ISO and IEC. There being no precedent, the group was referred to as the CEN/TC 114 Special Group (CEN/TC 114/SG). The group's European members obviously included most of the experts who had had a hand in framing EN 292:1991, resolved to ensure as far as possible that the resulting international standard met all the conditions applicable to the European standards that fill out a New Approach Directive.

Nearly seven years after revision got under way, when the final draft is set to be put to the formal vote by states through a "parallel" consultation at European and international level, there is every interest in taking stock of the problems faced, the progress made and the points on which it appears that the consensus reached is not the best possible.

4.2. Differing views on the allocation of manufacturer's and user's responsibilities

The European approach to this (discussed in point 3.2) took the US experts somewhat aback, as evidenced by a remark made in the first inquiry describing it as a "quirk".

It has to be appreciated that the European standards intended to facilitate the application of New Approach Directives :

- are inextricably linked to the Directives' requirements;
- can apply only to product design;
- cannot include provisions which must be applied by users, who are bound by regulatory requirements under European Directives which are entirely separate from the New Approach Directives.

Fortunately, the designer's obligation to provide information for use containing all the information needed for the user to apply the safety measures which could not be designed into the machine (see 3.1) ensures that the vital communication from designer to user takes place.

There is no international provision like the European New Approach which allows certain international standards to be associated to common legislative requirements, nor any obligation for states to incorporate standards which they have helped frame into their national collections. Outside of the system set up for the European New Approach, there is no reason why a standard should not be addressed equally to the designer and user of a product. It is also a fact that the limitations placed by the New Approach on the scope of standards (see paragraph two of this section) may be problematic for tackling certain issues[17]. The German design-integrated safety system, moreover, was long based on remarkable technical documents - *Unfallverhütungsvorschriften* - addressed to designers and users of many groups of equipment. There is still a mighty job to do before there is a really satisfactory world system for the regulation of safe machinery design.

17. For instance, where it is the user's rather than the designer's responsibility to apply a set of preventive measures (e.g., the collection of hazardous substances emitted by machinery).

The discussions ignited by the US proposals, which initially tended to disregard the European circumstances, resulted in a significant revamp of the schematic representation of the complementary roles of designer and user, discussed in point 3.1.; the new version, however (see Figure 2, p. 49), is still in line with the European requirements. Significantly, compared to the 1991 version (see Figure 1, p. 42) :

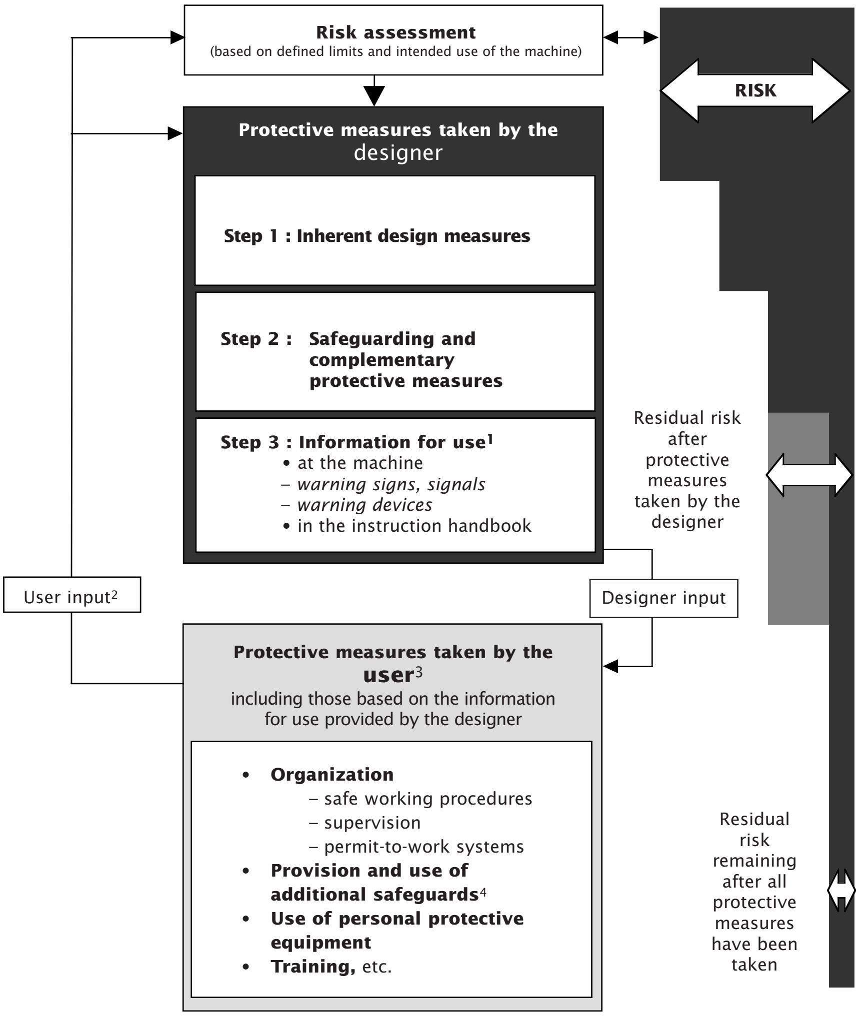
- the two spheres (of designer and user) are depicted as more evenly-balanced, although design is symbolically portrayed as being more important than use[18];
- the new representation brings out the user's input to machinery design and the designer's contribution to its use;
- important clarification is provided by the four notes to the Figure[19].

18. In the US's first proposed schematic representation, the "user" sphere took up nearly 2/3 of the page !

19. In particular Note 4, setting out conditions in which the user may add collective protective measures to the machine without falling foul of the safety integration rules.

The concepts of *residual risk after measures taken by the designer and risk remaining after all protective measures have been taken* gave rise to protracted and heated discussions, which is proof positive that the European way is not readily assimilated by some more used to other ways.

Figure 2 **Protective measures taken by the designer and by the user of a machine** (from Figure 1 in draft EN ISO 12100-1 dated July 2002)



1 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.

2 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.

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

4 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.

4.3. The concept of adequate risk reduction

Even the first incarnation (1991) of EN 292 showed - especially in the figure used to illustrate the three stage method - that the designer must not just aim to avoid, or if that is not possible reduce, risks, but to achieve an adequate risk reduction, i.e. reducing the risk in ways which do not adversely affect other aspects of use. When the standard was under revision, it became apparent that the explanatory footnotes to the Figure on the meaning of “adequate risk reduction” would be better incorporated in the body of the standard and expanded on. In the final draft (EN ISO/FDIS 12100-1), they are included in point 5.5 of the first part in the form of nine questions, each of which must be answered in the affirmative to be assured that the risk is being adequately reduced within the meaning of the standard.

The questions require the designer to satisfy himself that :

- all operating conditions and all intervention procedures have been taken into account in the risk reduction approach;
- the 3-step method has been applied;
- hazards have been eliminated or risks from all identified hazards have been reduced to the lowest practicable level;
- the measures taken do not generate new hazards;
- the users are sufficiently informed and warned about the residual risks;
- the operator’s working conditions and the usability of the machine are not jeopardized by the protective measures taken;
- the protective measures taken are compatible with each other;
- sufficient consideration has been given to the consequences that can arise from the use of a machine designed for professional / industrial use when it is used in a non-professional / non-industrial context;
- the measures taken do not excessively reduce the ability of the machine to perform its function.

From the start of the standard revision, some members of the special group pressed for the inclusion of the concept of *tolerable risk* within the meaning of ISO IEC Guide 51[20], defined as : “risk which is accepted in a given context based on the current values of society”. This gave rise to a long-running, heated debate

20. ISO IEC Guide 51:1999 Safety aspects - Guidelines for their inclusion in standards, whose scope can include a wide range of products and services where the discussion on risk reduction is much less advanced than that on machinery.

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21. Foremost among the opponents being the French Ministry of Labour.

between advocates and opponents of the concept[21]. The proposal was defeated chiefly on the grounds that the idea behind the concept *of tolerable risk* - that certain levels of risk could be accommodated indefinitely - was flatly opposed to the philosophy of EN 292 which calls for the solutions adopted to be constantly challenged in the light of technical progress. As a result, *adequate risk reduction* will remain the objective set for designers by draft EN ISO 12100-1.

Has this hard-won consensus drawn the debate to a close ?

There is no doubt that because of the different aspects that it brings into play on top of risk as such (see the nine questions, above), the concept of *adequate risk reduction* shows up the ISO IEC Guide 51 *tolerable risk* concept as crude or needlessly restrictive. But the third question, the only one specifically referable to risk reduction, is based simply on the idea of reducing the risk to the "lowest practicable level". This leaves the designer as the sole arbiter of whether to attempt to reduce the risk further by means which he can design and apply (safety integration), or whether he is morally justified in simply calling the attention of users of the machine to the residual risk by supplying them in the information for use with details of the means (personal protective equipment, in particular) by which to protect themselves from it ?

In the latter case, the preventive measures applied are not controlled by the designer. It is apparent, therefore, that the designer must be absolutely clear about what he can reasonably expect of the user so as not to recommend unrealistic measures which cannot possibly be applied.

It is important to stress that the emphasis which draft EN ISO 12100-1 puts on the user input to machinery design (see Figure 2, p. 49) is the product of a clash between two distinctly different cultures : European culture – so imbued with the importance of safety integration that it may tend to overlook the benefits of designer-user dialogue – and the American culture, where the allocation of responsibilities between designer and user is less rigidly defined.

4.4. Ergonomics and emissions provisions

The mechanical or electrical hazards of machine use were for long virtually the only form of risk on the public agenda and even, sad to say, that of some safety inspectors. In the closing decades of the twentieth century came a gradual awakening to the need to tackle other forms of machine-related hazard as well, which may be less starkly evident than mechanical or electrical hazards but still take a considerable toll :

- the severe risks created by the non- or mis-application of ergonomic design principles;
- the effects of emissions (noise, vibrations, radiation, hazardous substances).

A comparison of draft EN ISO 12100-1 and EN 292:1991 shows that the ergonomics provisions were not much developed by the revision. Is this really because the specialists who took part in the inquiries thought them still satisfactory in a form unchanged from ten years before[22] ? Or is it rather because the opinion of specialists who could have improved these provisions was not sought ? Japan was responsible for the only innovation in the standard - the definition and factoring in of the concept of *usability* of a machine.

Not so with emissions, where those – machinery manufacturers and safety inspectors, in particular – responsible for avoiding or alleviating their effects have not so far done enough to exploit the fact that these, unlike many other hazards, are always *measurable*. The efforts made in the 1990s to leverage this attribute, especially in standards, are reflected in draft EN ISO 12100-1 through numerous alterations and additions to the old provisions : the concepts of *emission value* and *comparative emission data* are defined, various provisions on estimating and reducing emission hazards are added to both parts of the standard. Significantly, extensive reference to *comparative emission data* is encouraged as one method of conducting the comparative approach referred to in draft EN ISO 12100-1, subclause 5.5, paragraph 1 :

22. The far-reaching scope of the standard means that the provisions of draft EN ISO 12100-1 must remain very general, so it may be that this level (broad principles) is not where the advances made in ergonomics during the 1990s are most apparent. The efforts made by ergonomists (especially those on CEN Technical Committee 122) to facilitate the use of ergonomics standards by machinery designers are to be remarked upon (and welcomed).

"The iterative risk reduction process according to 5.4 and figure 2 can be concluded after achievement of adequate risk reduction and, if applicable, a favourable outcome of risk comparison (see 8.3 of ISO 14121)."

4.5. Provisions on 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 that others (or the same ones) carry out lifting operations; the revision of EN 292, therefore, had to take this amendment into account.

The three chapters of draft EN ISO 12100-2, each corresponding to one of the three stages – inherent design measures, protection, information for use – of the method laid down in draft EN ISO 12100-1, rightly include many provisions specifically adapted to mobility or lifting aspects of machine operation, although without expressly using the words.

4.6. Why is the A-B-C structure no longer portrayed as a hierarchy ?

The European standards system buttressing the Machinery Directive's essential requirements was ill-advisedly presented in EN 292:1991 as an order of priority (type-A➤type-B➤type-C standards). The term "hierarchy" has been replaced in draft EN ISO 12100-1 by reference to an overall *structure* based on the three same types of standard. This change elicited some surprise, if not regret. However, the introductions to both parts of EN 292:1991 and draft EN ISO 12100-1 contain the statement that : "When a type-C standard deviates from one or more provisions dealt with by Part 2 of this standard or by a type-B standard, the type-C takes precedence". This clearly shows that it was never the standard developers' intention to make type-C standards absolutely subsidiary to the provisions of type-A and -B standards, nor type-B standards to type-A standards, in every case. The provisions of Part 1, i.e., the definitions of the *basic concepts* and the *design methodology* (see 3.1), are the only ones where no deviation is possible.

Horizontal standards are guidance for designers in how to apply the Directive's essential requirements. But guidance is not the same as compulsion. Thankfully, in most cases, there is no reason not to apply the Directive's requirements and the standards' provisions to the letter. Where a designer has good grounds for not following a requirement to the letter in particular circumstances[23], subject to implementing compensatory collective protective measures (see, e.g., the specific case referred to in 3.4), the horizontal standards provide the *benchmarks* – safety distances, ergonomic data, comparative emission data, etc. – needed to assess the importance of the envisaged deviation and whether or not to forego it in light of the risk assessment. The premise was that designers would be mindful of their responsibilities, and not abuse the leeway for judicious compromise with the ESRs and provisions of standards where needed. Where such instances arise, the proposed "case-specific" solutions should preferably be discussed in a working group by representatives of the parties concerned, and when consensus has been reached, validated by incorporation into a standard.

23. Envisaged in preliminary observation No. 2 of Annex I of the Machinery Directive.

5. Where does the workplace user come in ?

All those who put time and effort into framing standards that protect the health and physical safety of machinery users must be at all times concerned with the effectiveness and efficiency of their activity.

Are standards always reaching those to whom they are addressed : the engineers and technicians responsible for designing and improving machinery ? How are the messages conveyed by the standards taken on board in design offices ? How can the provisions of standards be continually improved to better achieve their objective ? In particular, is the experience of machinery users (operators, adjusters, maintenance and repair staff...) being leveraged to best effect, and where a machine does cause harm to the user, is every effort always made to investigate why and put the findings to use[24] to improve the provisions of the failing standards ?

The key role that technical education can and must play in seeing that standards do not go ignored up to a point is discussed elsewhere in this article[25]. The national standards bodies carry out periodic surveys to gauge the impact of standards on those to whom they are addressed.

As regards the ongoing improvement of standards to better achieve their objective, this clearly[26] depends mainly, as in any system of regulation, on the active feedback of information from the user community to the working groups that frame and revise standards. What is needed is proper, organized "standards maintenance" between inquiries, collecting constructive suggestions from remarks made by workplace users (at the start of revision of a standard, there is nothing more depressing than to open its file and find that no remarks have been made since its adoption, when particular failings of the standard have become glaringly obvious !). Thankfully, encouraging steps supported by national public authorities and trade unions have already been taken so that the present state of affairs does not go on forever.

To conclude on the inexorable shift of standards development and revision from the European to the world arena, I can do no better than to quote from Paul Makin, who was involved from 1985 in the development of several European standards (including EN 292), was a CEN and CENELEC consultant for the safety of machinery from 1992 to 2001, and chaired ISO Technical Committee 199 "Safety of Machinery" from its formation in 1991 until 2002 :

> "Nearly everyone involved in the production of safety standards agrees that the future lies in making standards at the international level – "do it once, do it internationally !". This is reflected within CEN and CENELEC where most new work and revisions of existing standards are planned as international (ISO or IEC) standards, under cooperative agreements.

24. Paragraph 5.1.4 of draft EN ISO 12100-1 refers to the role to be played by "the accident history and health records" in designing safe machinery. The express reference to machinery-related health damage is significant, since the emphasis was for long almost entirely on accidents.

25. See 3.5.

26. On this, see in particular point 4.4, above, on ergonomics.

However, it would be wrong to take the view that the future is bright for international standardization. There are some fundamental problems that standards bodies and national governments have to solve.

The first one is that to be truly global the standards have to be developed and accepted by all countries, and that is not the case at the moment. Standardization both generally and within the machinery sector is a rich countries club. It requires a well developed national standards structure to participate at the world (ISO / IEC) level. It also requires national organizations who are prepared to send experts to the meetings – which are almost inevitably somewhere else in the world. These requirements exclude most developing countries who do not have the necessary resources in money and expertise and will continue to do under the existing arrangements for writing standards. Lest we are too complacent let us also understand that within Europe many interest groups are also excluded from the standardization process. For example, few working groups have an input from workers' representatives or from consumer groups. The same applies to SMEs – the very organizations that were expected to benefit from the new standardization process[27]."

27. Taken from a paper entitled *The growing importance of international standardization - Developments in the machinery sector* given by Paul Makin on 11 October 2001 at the *Berufsgenossenschaftliches Institut Arbeit und Gesundheit* (Dresden) to the European conference "Standardization, Testing and Certification - A Contribution to Occupational Health and Safety", jointly hosted by KAN (*Kommission Arbeitsschutz und Normung*), BG-Prüfzert, INRS and EUROGIP.

Machine safety-related control systems : opportunities and challenges for CEN and IEC

By Maurizio D'Erme *

1. EN 954

Standard EN 954 forms part of the CEN framework of standards (e.g., EN 292, EN 1050) which create a linkage between type-A and type-C standards and so fulfils an essential role in the standards supporting the Machinery Directive. It is developed by CEN/TC 114 - CNL/44x JWG6 "Safe control systems".

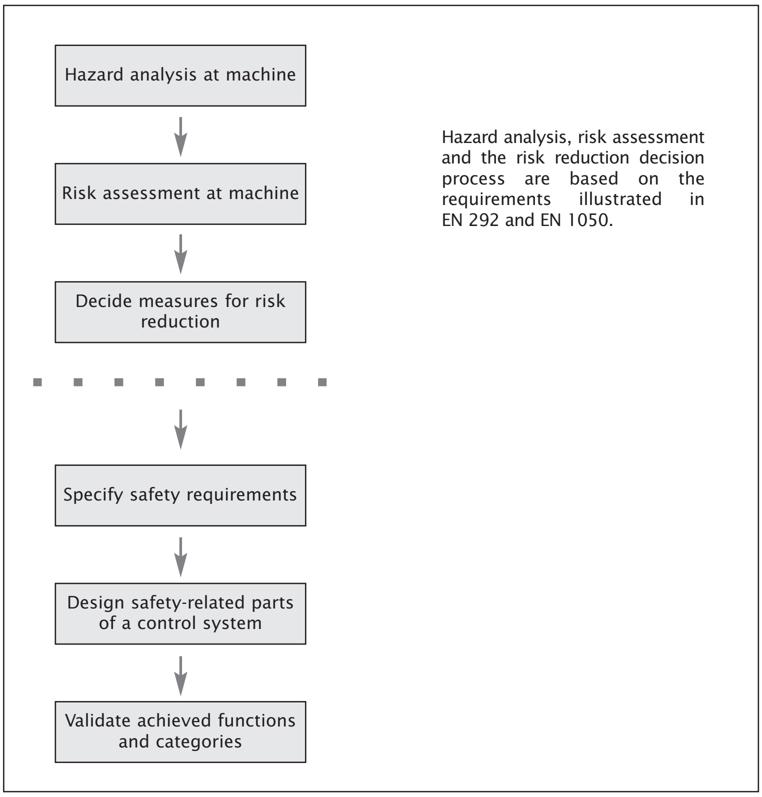
Harmonization work on EN 954:1996 *Safety of machinery – Safety-related parts of control systems – Part 1: General principles for design* has been ongoing since 1996. A new Work Item, WI 00114071, was established to amend EN 954-1 under the Vienna Agreement with CEN as lead agency, the aim being to have the CEN Enquiry launched by October 2002, and the Formal Vote by April 2004. It will be numbered EN ISO 13849-1.

PrEN 954-2 *Safety of machinery – Safety-related parts of control systems – Part 2: Validation* is currently being assessed by CEN consultants with a view to the forthcoming Formal Vote procedure. It will be numbered EN ISO 13849-2.

EN 954-1 addresses the design of safety-related parts of machinery control systems (Figure 1, p. 65, taken from prEN ISO/FDIS 12100-1:2001), regardless of the technology used, and most notably PESs (Programmable Electronic Systems).

* Engineer, former senior official at ISPESL *(Istituto Superiore per la Prevenzione e la Sicurezza del Lavoro)*, Italian representative in the Working Group JWG 6 of CENELEC TC 44x - CEN/TC 114 (in charge of preparing EN 954 parts 1 and 2).

EN 954-1 proposes the following iterative design strategy :



EN 954 states that designers should construct safety-related parts of control systems to meet the requirements of one or more of five performance categories.

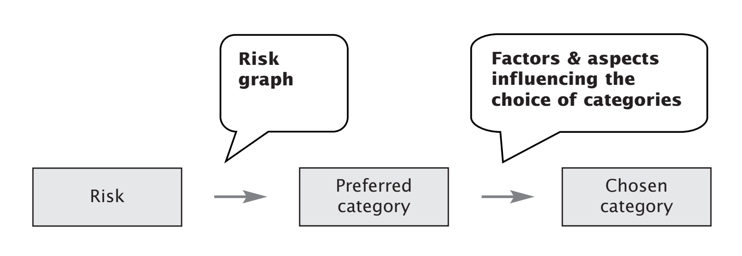
Each category is defined in respect of its resistance to faults and its subsequent behavior in fault conditions. Categories are allocated by reference to a risk graph, a risk-based approach to determine the appropriate design category for safety-related parts of machinery control systems.

The risk associated with a particular situation or process can be represented as an equation where :

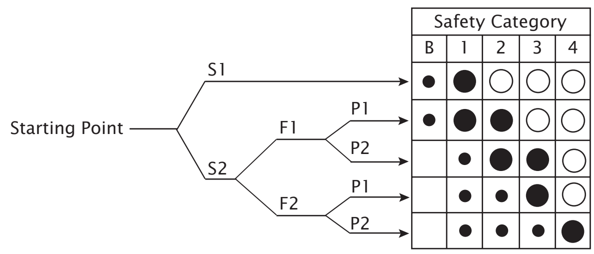
Risk = Severity + Probability + Frequency

The risk graph is only guidance (not a substitute for meeting the standard) to help designers choose a category based on a risk assessment.

The selection process can be summarized as follows :



In practice, component reliability, the technology used, and the particular application may result in a choice of category other than that expected.



Selection of the Safety Category :
A brief overview of these safety categories is provided in Figure 11.

- ● Preferred categories
- • Possible categories, which require additional measures
- ○ Over-dimensioned measures for the relevant risk

1.1. EN 954-1 - Expectations and disillusions

Insight into the limitations of EN 954 will be gained from a consideration of the reasons for developing both EN 1050 and EN 954.

EN 1050 illustrates general principles for risk assessment based on the assumption that risks distribute according to a scale of rising levels. This standard was intended to establish a risk classification based on the probability of occurrence of possible harms and the severity of their consequences. The risk classification would be the benchmark for the adoption of corresponding technical measures.

The basis of EN 954-1 is consolidated (EN 60204-1[1]) fault control concepts, the intention being to set criteria for classifying safety-related control systems according to a scale of increasing safety expectation.

1. EN 60204-1:1997 Safety of machinery - electrical equipment of machines - Part 1 : General requirements.

Taking both standards together would have forged the linkage between the *risk* level and the *safety* level required for control systems : in particular, low-risk applications would have been associated with simple electromechanical circuits, while high-risk applications would have been associated with electronic components which continuously monitored system safety.

The first aim to fail was that of achieving an objective classification of risks : in fact, even the *possibility* of framing a standard on this issue was thrown into question. It was argued that the standard could allow less exacting manufacturers to stop short at a certain risk level instead of going further in the search for lower-risk applications.

When EN 1050 was published, it was made clear that it conferred no presumption of conformity with EHSRs, so that a manufacturer's declaration of having followed EN 1050 would not relieved him of his duty to carry out a risk assessment.

At the start of work on EN 954, it seemed that framing a standard on consolidated principles of fault control would be an easy task. The working group of experts first defined a number of categories expressing the required fault-resistance behavior of the safety-related parts of a control system. This comprised a basic Category B, followed by Category 1, 2, 3 and 4, characterized by improved fault-resistance. This was an unfortunate choice, since it created the misconception that the categories were in some way linked to the magnitude of risks, with greater risks assigned to higher categories !

Other working groups began to use the categories developed by JWG 6, often incorrectly, requesting their machines to be classed in categories 3 or 4. Meanwhile, JWG 6 encountered problems in applying the three premises which underpinned its work, namely *the ability to assign a specific category to a control circuit, the ability to use categories to illustrate a hierarchy of technical solutions, and finally the ability to check the attribution of categories.* Further difficulties related to the definition of reliability criteria for electronic components, and whether safety functions could be assigned to them.

As a result, JWG 6 changed the title of the standard, limiting the scope to “safety-related parts” of a control system. It was also made clear that the categories were not intended to be used in any given order of priority in respect of safety requirements : the experts were aware of the misconception that greater risks would require higher categories.

The elements presented in this paragraph will be illustrated in the following pages by means of practical examples.

1.2. Machinery risk assessment : the role of EN 954-1

A mechanical example will now be examined to show the reasoning behind the technical solutions chosen by machinery designers, particularly in relation to safeguards. A hydraulic press will be analyzed to show that even the simplest machine presents different risks.

1.2.1 Simplified risk assessment for a hydraulic press

In machinery risk assessment, the first step is to identify and evaluate the hazards on the machine by reference to the process which the machine is intended to carry out.

Hazard identification at machine

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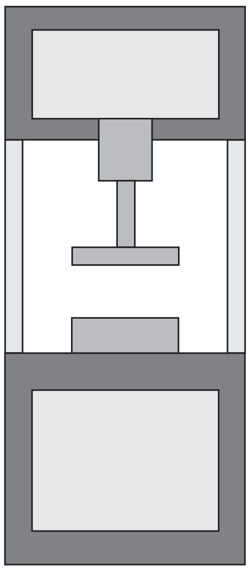
The hazard identification can be performed following the guidance in EN 292-1 and EN 1050.

In the case of a simple hydraulic press, the designer may take into account mechanical and electric hazards : an unguarded stroke, a guard failure, an electric shock during maintenance, etc.

On the basis of these hazards, the designer estimates the risk in terms of the severity and the probability of occurrence associated with the selected hazards, in order to decide what if any appropriate risk reduction measures are needed.



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Risk estimation and evaluation at machine

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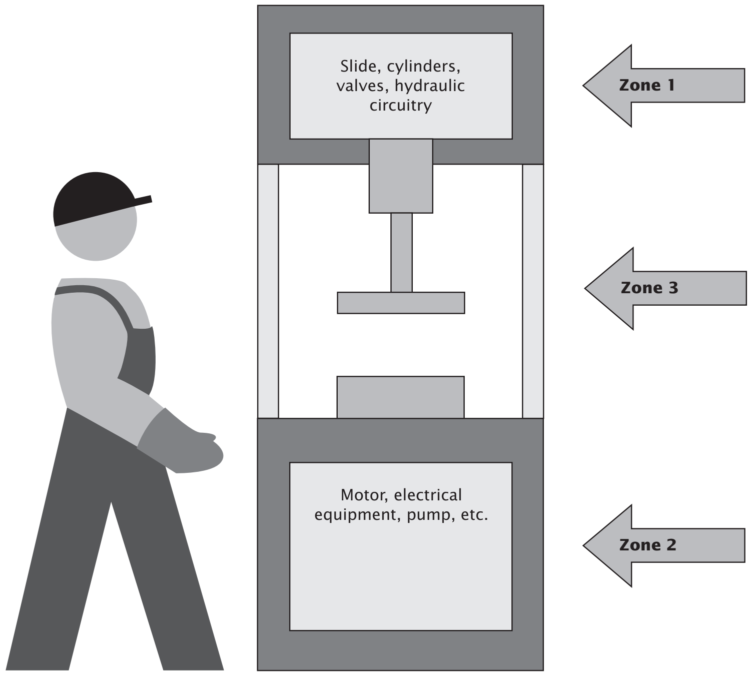
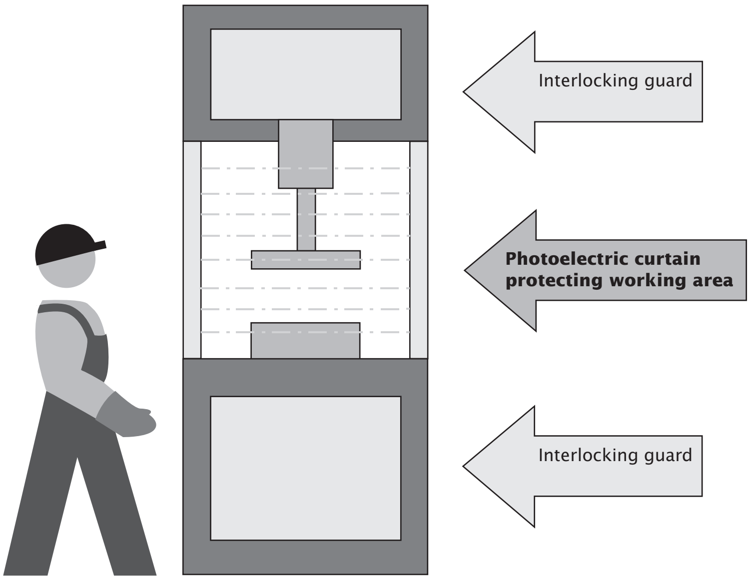
Choice of measures for risk reduction

↓

Three main danger zones can be easily identified during the Hazard Identification phase :



- **Zone 1.** contains the hydraulic circuit : it is a low-risk area, which does not require frequent access for inspection and maintenance. In general, the hydraulic system in the first danger zone may present mechanical hazards from high-pressure fluid ejection, thermal hazards from contact with piping and devices, and impact hazards. The designer may opt for an *interlocking guard*.
- **Zone 2.** The electrical equipment in the second danger zone is a medium-risk area where access may be more frequent, and electrical hazards are present through contact with live electrical devices. Here, too, the designer may opt for an *interlocking guard*.
- **Zone 3.** The third danger zone is the tools (or working) area - a high-risk zone to which the operator requires continuous access. It mainly presents crushing and impact hazards from slide movement : gravity fall or unintended start-up may result from a hydraulic system, mechanical, electrical control system, or sensor failure. The designer may choose to fit an Electro Sensitive Protective Device (ESPD).



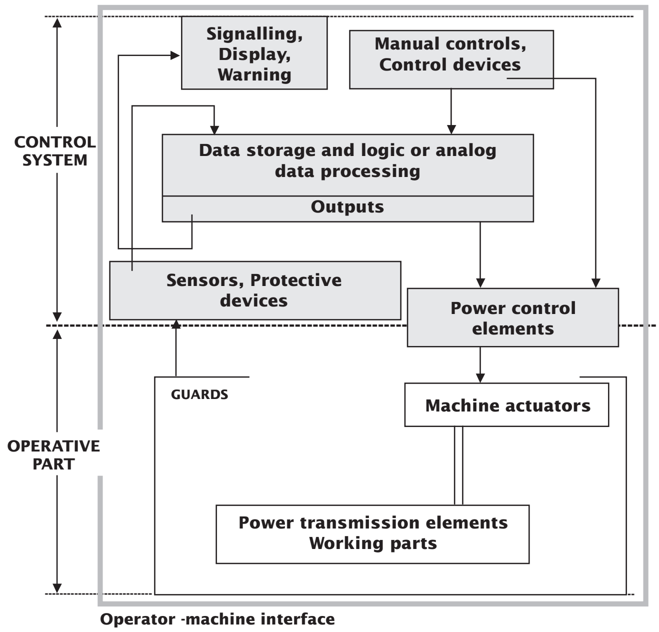
The risk assessment shows that the three main danger zones of the hydraulic press present significant hazards, which must be dealt with by appropriate preventive measures.

Even the simplest machine presents different risk levels.

Some of these risks, as in the example, have been reduced by *controls* : the designer has assigned some *safety functions* to some *parts* of the control system, the so called Safety-Related Parts of Control System (SRP/CS) : start and stop functions, control mode selection, alarms, isolation and energy dissipation, muting, are all examples of safety functions.

Figure 1 **Schematic representation of a machine**

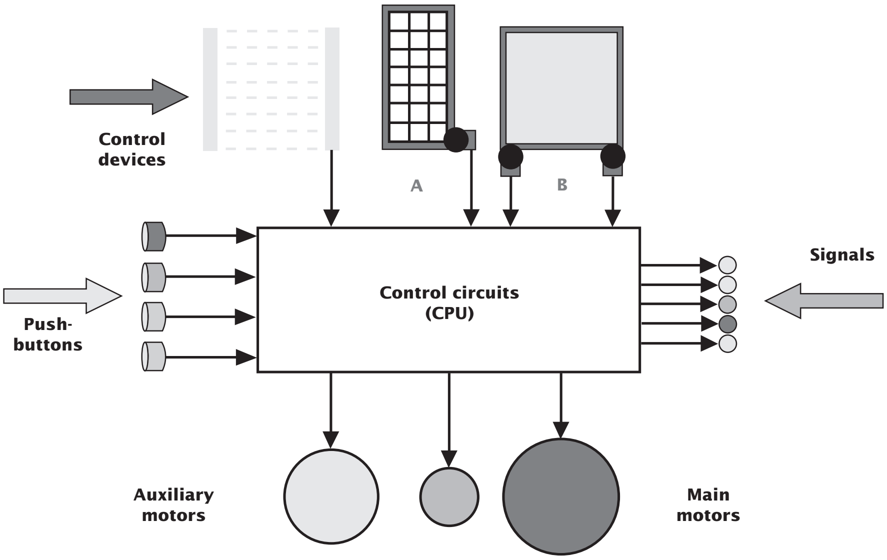
The SRP/CS must be distinguished from other parts of the control system which are not relevant to safety, as well as from all other machine parts.



While this distinction is correct in principle, it should be borne in mind that the designer allocates safety functions to the control system as a combination of communicating hardware and software, with separate and/or integrated components.

This aspect can be better illustrated by looking again at the hydraulic press. Here, the designer may decide to provide a start function, and a stop and emergency stop function associated with a guard opening, for example.

This decision will result in a provisional design for safeguarding the machine, which may include guards, stop buttons, relays, photosensitive devices, etc., as illustrated in the diagram below :



Even the simplest machine's control system carries out different functions, each controlled by a specific combination of hardware and software elements.

In the hydraulic press, the operator acts on push button controls. Machinery sensors verify the operating conditions (in terms of temperature, pressure, correct position of the tool). The guards A, B and the ESPD control the safety conditions.

All these signals go to the control system (CPU - Control Processing Units), which processes them, sends start or stop commands to all moving parts, and activates all functions.

Some aspects of the control system's reaction are not directly safety-related (e.g., cooling and lubricating functions), while others, such as cycle initiation, are.

In specific operating phases, too, the control system inhibits various safeguards, such as in "muting", which is a temporary automatic suspension of a safety function.

The control system architecture is another important consideration. In general, both *separate* and *common* sub-components, wirings, cables, switches, relays, are used when designing the machinery control system, which may be seen as a single entity reacting to different operating conditions, events and safety requirements.

Bearing all this in mind, the following conclusions can be formed at this point in the analysis :

- All machines have an identifiable control system.
- Even a simple machine – like a hydraulic press - presents a range of risks.
- The designer may reduce some of these risks by using parts of the machine control system to perform safety functions. These parts are known as Safety-Related Parts of the Control System (SRP/CS).
- Even if the interfaces between the SRP/CS and all other machine parts can be identified, the machine control system – shown in Figure 1, p. 65 – is a single entity consisting of different components which may be integrated or separated to react to different operating conditions. *In other words, the machine control system cannot be characterized by a single function and a single behavior.*

1.2.2. Moving toward EN 954-1

Once the designer has decided to reduce some of the machine's risks by using parts of the machine control system, a risk evaluation and estimation helps decide *what contribution each SRP/CS will make to the reduction of these risks.*

Obviously, the more closely-dependent risk reduction is upon the SRP/CS, the greater the fault-resistance of those parts must be.

So, depending on the risk-reduction role played by each SRP/CS, different fault *behaviors* must be selected for those SRP/CS.

This is where EN 954-1 comes in. What EN 954-1 does is to introduce a "language" of five categories for describing how SRP/CS should perform in relation to the occurrence of faults. It classifies SRP/CSs by their fault-resistance and subsequent behavior in the fault condition.

Table 1 **Summary of requirements for categories**

Category	**Summary of requirements**	**System behavior**	**Principles to achieve safety**
B	Safety-related parts of control systems and/or their protective equipment, as well as their components, shall be designed, constructed, selected, assembled and combined in accordance with relevant standards so that they can withstand the expected influence.	The occurrence of a fault can lead to the loss of the safety function.	Mainly characterized by selection of components.
1	The requirements of B shall be met. Well-tried components and well-tried safety principles shall be applied.	The occurrence of a fault can lead to the loss of the safety function but the probability of occurrence is lower than for category B.	
2	The requirements of B shall be met and well-tried safety principles shall be applied. The safety function shall be checked at suitable intervals by the machine control system.	– The occurrence of a fault can lead to the loss of the safety function between the checks. – The loss of the safety function is detected by the check.	Mainly characterized by structure.
3	The requirements of B shall be met and well-tried safety principles shall be applied. Safety-related parts shall be designed, so that : – a single fault in any of these parts does not lead to the loss of the safety function; and – whenever reasonably practicable the single fault is detected.	– When the single fault occurs the safety function is always performed. – Some but not all faults will be detected. – Accumulation of undetected faults can lead to the loss of the safety function.	Mainly characterized by structure.
4	The requirements of B shall be met and well-tried safety principles shall be applied. Safety-related parts shall be designed, so that : – a single fault in any of these parts does not lead to a loss of the safety function; and – the single fault is detected at or before the next demand upon the safety function. If this is not possible, then an accumulation of faults shall not lead to a loss of the safety function.	– When the faults occur the safety function is always performed. – The faults will be detected in time to prevent the loss of the safety function.	Mainly characterized by structure.

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Table 1 contains the general principles for control functions in the event of failure as determined by the structure and/or reliability of these SRP/CSs.

The ability of the SRP/CS to resist faults depends both on the reliability of the components to *avoid* faults, and the arrangements of the components in the SRP/CS *to avoid, tolerate or detect* faults : these concepts were clearly illustrated in EN 60204-1, 9.4. “Control functions in the event of failure”.

Consequently, the designer must take a decision as to both the *components* and the *structure* of the SRP/CS, on the basis of the desired fault- resistance behavior of the SRP/CS.

Inherent design measures applied to control systems are intended to “control” failures. In general, these failures are controlled either by using proven circuit techniques and components, or by taking measures to neutralize failures before they generate a hazardous condition, or cause damage to the machine or the work in progress.

Avoiding faults may be appropriate in case of simple and consolidated technologies and applications (mechanics, hydraulics, electrical engineering, hard-wiring). In some cases, as for start and stop push buttons, there is no other feasible design choice.

But where new or complex technologies (e.g., multi-component and hybrid electro-technology) are concerned, it may be better to improve the *structure* of the SRP/CSs in order to *avoid, detect, or tolerate* faults. To this end, practical measures to minimize risk in case of faults include redundancy, diversity and monitoring.

An important conclusion can now be drawn :

> The control system performs the safety functions by using its hardware and software components (SRP/CSs) separately or in combination, so that even the simplest machine control system cannot be characterized by a specific fault-resistance or single behaviour against faults, i.e., by a single category.

Taking this conclusion together with that drawn on page 59, the claim : “The hydraulic press is dangerous and needs a category 3 control system” can be said to be meaningless.

2. EN 61508 – 62061

Standard IEC 61508 *Functional safety of electrical/electronic/ programmable electronic safety-related systems* – developed by IEC/TC 65 “Industrial process Measurement and Control – System Aspects” – was published in 1998. The CENELEC Technical Board ratified the seven parts of IEC 61508 in July 2001, the standard was published as EN 61508 in August 2002. Any conflicting national, CENELEC or CEN standards must be withdrawn by August 2004.

There are no plans to harmonize the standard under any EC Directive.

IEC 61508 covers the safety management of electrical, electronic and programmable electronic systems throughout their lives from concept to decommissioning. It brings safety principles to the management of systems and safety engineering to their development.

It is a generic standard which might not easily apply to specific applications like machine control systems.

This situation has been brought about by the new draft standard IEC 62061 *Safety of machinery. Functional safety or electrical/ electronic/programmable electronic control systems.* It should be stressed that IEC 62061 is still at an early stage of development, but it is already clear that it is intended to be specific to the machine-building sector.

The intention is that IEC 62061 will adapt the requirements of IEC 61508 to the machinery sector, at the same time using the EN 954 requirements to inform the process of designing a control system to meet the safety integrity level requirements for those safety functions that the control system is performing. Draft

IEC 62061 is therefore acting as an "integrating standard" to put EN 954 to more practical use within the philosophy of IEC 61508.

It is important to note here that it may not be the purpose of draft IEC 62061 to change the relevant requirements laid down in IEC 61508 : the machinery-specific issues will only *reduce* the global view of the generic standard to the machinery-specific aspects.

This conclusion has a number of significant implications. IEC 61508 requires that a safety integrity level (SIL) be allocated to safety-related control functions. *The SIL is one of four discrete levels, each corresponding to a range of target likelihood failures of a safety function*. In order to allocate safety integrity levels which have a quantified probability of *failure to danger*, the standard suggests a structured approach to quantifying risk through procedures derived from a generic fault tree model of accident causation. *The probability of an accident of a particular severity occurring (the top event) is a combination of the probability that the accident will occur and that it will result in an injury of a particular severity level*. Using look-up tables, the accident causation logic leads to a required risk reduction to be achieved by each safety-related control function.

The target SIL can then be determined by establishing an acceptable level of risk reduction according to defined risk criteria.

The main problem with a quantitative approach to risk assessment, as described in IEC 61508, is the availability of suitable data. Two types of data are required :

- **Failure rate data for the components and subsystems**. It may be necessary to use data from generic components, or for outdated components; however, data can be obtained (or estimated) for most components, although it is likely that some assumptions may have to be made.
- **Levels of acceptable risk**. The level of acceptable risk is a societal parameter and is difficult to determine, being dependent on perceived, rather than actual, risk. The guidance in IEC 61508 uses the ALARP value but gives no help in determining what

that value should be. Then, how to make assumptions about hazard rates ? This may be the most problematic aspect of using IEC 61508 until industry-specific guidance documents, based on IEC 61508, give pointers in this area. Even then, publishing such guidance may create apprehension among risk groups.

A number of assumptions had to be made in order to perform the quantitative analysis described in IEC 61508. These were subjective and had a significant effect on the SILs. The quantitative analyses of many other systems may be highly reliant on basic (and possibly subjective) assumptions. Some of these may be difficult to challenge, and could mean that failure-rate predictions will be distorted to meet the needs of other agendas.

Draft standard IEC 62061 is being developed as a new international standard for safety-related control equipment of machinery. It is being framed under the umbrella of IEC 61508 and will integrate the principles of EN 292 (ISO/TR 12100), EN 1050 (ISO 14121) and EN 954 (ISO 13849). The standard will describe an approach for risk assessment and specification of the safety requirements for control equipment, which is based on the principles of IEC 61508 and takes into account the requirements of EN 292 and EN 1050.

The standard is intended to give guidance for the design of safety-related electrical control systems using simple electromechanical devices as well as complex programmable electronic systems. The methods are based on IEC 61508 with the intention of factoring in the deterministic approach of EN 954. Methods for determining the safety performance of the control system and achieving the required risk reduction will be given.

2.1. IEC 61508 - Expectations and disillusions

The experts disappointed by the limitations of EN 954-1, particularly in relation to PESs, rallied to the new IEC 61508 immediately it was put forward for enquiry. The first consequence was the inclusion of references to IEC 61508 in many Declarations of Conformity and, what is worse, in Certificates from Notified Bodies.

The standard's general impression is one of coherence and completeness : it is replete with numbers, diagrams, schematics, and tables.

More particularly, it provides concrete examples for control circuit design which appear to exactly match the categories familiar to EN 954-1 users. It also establishes a clear reference hierarchy for the Safety Integrity Levels, addresses the problems of PESs, and links the classification of control systems to specific numerical reference values.

However, it rapidly becomes clear that IEC 61508 uses a completely different language from that used for machinery. This should not come as a surprise, since the standard emanates from a Technical Committee whose remit does not include safety of machinery. In addition, it was developed to address the reliability of data transmission.

The big question, therefore, is whether IEC 61508 is to any extent applicable to machines, and whether it can coexist with EN 954.

A working group was set up to address these issues, and the experts working on a critical analysis of IEC 61508 were soon confronted with a number of difficulties. Broadly-speaking, there are conceptual differences in the approaches taken by IEC 61508 and EN 954-1 to achieve safe operation. It is neither correct nor possible to create linkages between SIL and Categories.

Many concepts developed in IEC 61508 cannot be applied to safety of machinery : a number of the control circuit schematics and practical examples just do not apply. In a nutshell, IEC 61508 can be said to deal with the *integrity of a signal*, and follows it from source to point of use. *It can be compared to dealing with the safety procedures for a train comprising a single coach, moving on a single track, carrying just one passenger*. Using a similar analogy, safety of machinery, by contrast, is about dealing with the safety procedures for a *four-lane motorway, with bridges and intersections* !

With respect to PES, *there is still no answer to the main question of whether – and in what conditions – PES can be applied to the safety of machinery*.

3. The way forward for EN 954 and IEC 62061

3.1. Intrinsic safety v Functional safety

Safety comes in two flavours :

- **Intrinsic safety** (e.g., EN 60204-1, EN 294, EN 349, EN 811) covers hazards such as electric shock, fire, cutting, crushing, and pinching.
- **Functional safety** (e.g., EN 954 and parts of EN 292) covers the safety hazards and risks related to the correct functioning of equipment.

The main added value provided by EN 954-1 is the exhaustive analysis of the three strategies to minimize risk in the event of failure, as introduced in EN 60204-1:1997: use of proven circuit techniques and components, provisions for redundancy, functional tests. EN 954-1 has been described as the “bridge” between intrinsic and functional safety.

EN 954-1 is the ultimate guidance on the procedure for designing machinery control systems, the faults which should and should not be dealt with, and demonstrating that a particular reliability objective has been achieved. *It does not provide solutions, but rather points the way towards them.*

Categories are an important and welcome introduction : their rigid classification is not helpful, and probably misguided.

The analysis and control of faults is rigorous. But this systematic approach is unsuited to systems of increasing complexity. In particular, EN 954 is not applicable to a single complex electronic system : the consideration of systematic faults is incomplete, and software aspects are not sufficiently addressed by EN 954-1.

The application of EN 954 alone is not sufficient for the validation of complex electronic systems. It must be recognized that new, different means and tools are needed for such systems.

3.2. Solutions ?

Functional safety is important because of the increasing number of control systems using PLCs (Programmable Logic Controllers) and computers. Serial-bus-based systems are now available to control safety guarding and interlocking, which are clearly safety critical. But there are safety implications to PLC and computer malfunctions. Technical glitches and software bugs may cause mechanical operations to happen out of sequence or override their end stops; software crashes can leave the control outputs in any combination of states, including “forbidden” ones. Designers should take all the possible failure modes of their PLCs and computers into account when performing their hazard and risk assessments under Safety of Machinery Directive 98/37/EC.

The current revision activities on EN 954-1 are intended to clarify a number of aspects of the previous version, and to establish a link with some elements of IEC 61508.

I have some concerns about the validity of attempting to merge elements which stem from two different philosophies and are directed to two different ends. In particular, EN 954-1 works from the assumption that if a failure is possible, it will occur sooner or later. The *deterministic* approach dictates a need to design the control system so as to react to failures and neutralize dangerous outcomes. IEC 61508, by contrast, introduces the notion of safety integrity, where integrity represents the *probability* that a safety-related system will perform the required safety-related functions in a satisfactory manner under the specified conditions and within the specified duration.

The main problem with the application of EN 954-1, furthermore, is the detailed understanding of its concepts : to modify the standard without having exploited the whole range of possibilities could be counter-productive. It is true that the correspondence between a given level of risk and a category in EN 954-1 is relatively flexible : however, the numerical values introduced in IEC 61508 have no “value” unless the standard is precise about where the value derives from, how it is measured, with what tools, what errors it can be affected to, etc.

On the other hand, even though it does not cover machine systems, **IEC 61508 – 62061** does represent a very good starting point for addressing complex electronic systems that fall outside the scope of EN 954.

But there are significant limitations in terms of applicability to safety of machinery. Both documents endorse the idea of quantifying a number of variables associated to control systems, but the criteria given to justify and verify such quantification are not sufficient.

Finally, the new concept of "lifecycle" in IEC 61508 should be better formulated, given the importance of the need to extend the analysis and control of the reliability of the system to the entire process of design and production. In fact – barring a few instances of "closed" components like immaterial barriers – it does not seem applicable to the great majority of machines, which are not produced in series, and cannot be locked into the rigid framework of the "lifecycle" approach.

Standards on mental workload
the EN ISO 10075 series : from ISO to CEN

By Friedhelm Nachreiner *

1. Standardization in the field of mental workload

International standardization in the field of mental workload was initiated in 1981 by an ad hoc group of ISO/TC 159 "Ergonomics" (Technical Committee 159 of the International Organization for Standardization). It was felt at that time that a more detailed standard on mental workload was needed as coverage of this subject in the basic standard ISO 6385:1981[1] *Ergonomic principles in the design of work systems* was fairly rudimentary and not in line with the growing importance of mental workload in the design and operation of work systems. Mechanisation, automation, and especially the introduction of new technologies had already led to changes in working conditions, placing increasing demands on mental performance at the work place. A standard was therefore needed that would introduce terms and concepts of mental workload, design principles and methods of assessment of mental workload to system designers and work system users, who were and still are fairly unfamiliar with mental workload concepts and issues. This can readily be seen from closer inspection of actual design solutions of existing work equipment or work systems, especially so in some areas where mental workload would appear to be of particular relevance, such as software design.

1. ISO 6385 is currently under revision (ISO/DIS 6385:2002). The process is in parallel with CEN (prEN ISO 6385) with ISO taking the lead. The next step will be the formal vote, expected in April 2003.

Another point in the discussion about the desirability of such a standard was that it might be helpful in health and safety regulations and in social partner negotiations on the design of working conditions. This seems to have gained in importance in

* Work and Organizational Psychology, Carl von Ossietzky Universität Oldenburg, Germany.
Friedhelm Nachreiner is Convenor of ISO/TC 159/SC1/WG2.

recent years, especially in connection with EU directives, where mental workload has emerged as an important topic (e.g., the Framework, Machinery and Working Time Directives). These European regulations that make explicit references to mental workload or stress have increased the political importance of standards. This can be seen, for instance, in the voting procedure in the FRG, where the standard on design principles (ISO 10075-2) had a trouble-free passage at the international level, whereas at the European level, some 60 employers' federations and big companies opposed it. The reason for this is quite simple : while an international standard does not have to be implemented into the national collection of standards, a European standard does, making it potentially relevant for socio-political negotiations or even decisions on the design, operation or evaluation of work systems. And since the directives - and their national implementing instruments - are often not very specific, European standards on the matter would seem a good and helpful means of specifying or interpreting the directives' rules, like for the VDU Directive, since standards represent a consensus on the state of the art. As can be imagined, this has not facilitated standards development, quite the reverse. The development of ergonomic standards, especially those on mental workload, has become (at least in some countries) a political issue, since their effects can be quite far-reaching.

Be that as it may, the development of standards on mental workload began in 1986, with the aim of helping those concerned with these problems, and the EU directives not being issued at all. For this reason, the decision was made within the relevant ISO committee (ISO/TC 159/SC1/WG2) to first develop a standard on terminology and basic concepts in order to facilitate a common understanding and usage of terms. This seemed and still seems to be of particular importance, since the use of terms like “mental stress”, “strain”, “fatigue”, etc., is quite inconsistent, not just in colloquial language, but in the scientific literature, too. Another reason to focus on such a standard first was the fact that mental workload issues are somewhat more complicated than physical workload problems, since different effects are produced by different kinds of working conditions. This standard on basic concepts and terminology relating to mental workload was published in 1991 as ISO 10075. It was adopted as a European standard (EN ISO 10075-1) in 2000 by CEN, the European standardization committee, and has to be implemented into the national standards collections of the CEN members.

In 1989, after part 1 was voted through, some countries in TC 159 expressed an interest in having a standard that would go beyond terminology, e.g., on guidelines for design and diagnostic methods for verification, that resulted in a relevant TC decision.

Part 2 of ISO 10075 was developed right from the beginning in WG 2, with no national standard or draft standard as input. Inputs were received, however, from different member bodies, ranging from suggestions on a suitable structure to limits of acceptable workload (in bit * sec $^{-1}$)[2 3]. After considering possible alternatives, WG 2 decided to prepare a general standard, providing guidelines with broad applicability rather than a standard laying down specifications on acceptable levels of mental workload. Such a standard seemed both too specific and likely to arouse political controversy at the time, whereas a standard laying down guidelines for the design and operation of equipment and work systems would be both more indicated, more effective and less subject to political dissension. Drafting the standard took comparatively little time, so that voting on the DIS took place already in 1995, again garnering substantial support (92 % positive votes) from the member bodies and only one negative vote (USA).

ISO 10075-2 was published in 1996 and deals with guidelines for design, since the working group responsible for development of the mental workload standards concluded that this was what was needed next : advice on the design of work tasks, equipment and environment with regard to mental workload, before trying to standardise requirements concerning measurement procedures. By specifying design principles that would optimise mental workload it should also become clear where these principles have been violated and corrective measures are appropriate or required. This made the standard an important political issue, resulting in discussions on its desirability - at least in the FRG - when it came to the European voting procedure. The standard

2. Definition : "A bit is the quantity of information conveyed by one of two alternative statements", Shannon, C. E. and Weaver, W.: *The mathematical Theory of communication,* University of Illinois Press, Urbana (1949).

3. This theory has its limitations when applied to human beings since the full significance of a stimulus conveying information cannot be interpreted by information theory (Etienne Grandjean, *Fitting the task to the man, A textbook of occupational ergonomics,* Taylor & Francis, 1988).

was adopted at the European level by a large majority in 2000 and again has to be implemented into the national standards collections of the CEN members.

With Part 2 yet unfinished, WG 2 started in 1995 on a Japanese first proposal for Part 3 on diagnostic methods and assessment procedures. This looks set to become the most complicated part of the 10075 series, since WG 2 had lengthy discussions about what might be feasible and acceptable as a standard on that topic. Again political considerations have to be taken into account, at least in Europe, where European Directives on machinery design and safety and health at the work place explicitly mention mental workload as a criterion to be observed. Thus, standards on mental workload could potentially be used to support or to fill out these directives. Therefore, as will be readily appreciated, trade unions and especially employers' associations keep a watchful eye on ongoing developments. Standardising certain forms of measurement of mental workload, so the argument goes, could be a costly affair as employers might then be forced to apply such methods to prove compliance with the directives or their national implementing instruments (whereas the benefits for employers and manufacturers resulting from improved working conditions or usability of products tend not to be mentioned or even denied). So it was argued that such a standard on diagnostic methods and assessment procedures should not be prepared at all.

Part 3, which is concerned with measurement aspects (in fact, requirements for measurement methods), has recently passed voting (enquiry) within ISO/TC 159/SC 1. CEN/TC 122/WG 2 is the responsible working group for the work item at the European level. After having considered the comments on the working draft, the ISO/DIS version was prepared and sent to the ISO Central Secretariat for the launching of a parallel enquiry (ISO lead). If this is also successful, Part 3 will be published as an International Standard and as an EN standard in the near future.

Meanwhile, a revision of Part 1 might be called for, in order to update it to recent developments in other areas of standardization, e.g., the current revision of the basic standard ISO 6385.

Rather than a detailed analysis, what follows is an outline of the contents of Parts 1 and 2 in their published versions and of Part 3 as it stands today. As far as can be seen, this will most probably also be the content of the final version, at least in general and except for some further editorial changes.

2. ISO 10075:1991 Ergonomic principles related to mental workload - Part 1: General terms and definitions

ISO 10075:1991 (or EN ISO 10075-1:2000, i.e. Part 1 of this series of standards with the number 10075) deals with terminology and basic concepts in the field of mental workload. Although mental workload is usually associated with tasks requiring information processing, the standard makes clear that any human activity, even those primarily regarded as physical activities, includes mental activities and thus mental workload. It is thus emphasised that this standard is *relevant to all kinds of work design*, not just to those kinds of work tasks which would be regarded as cognitive or “mental” in a narrow sense. Mental within the meaning of this standard refers to cognitive, informational, and emotional processes in the human being.

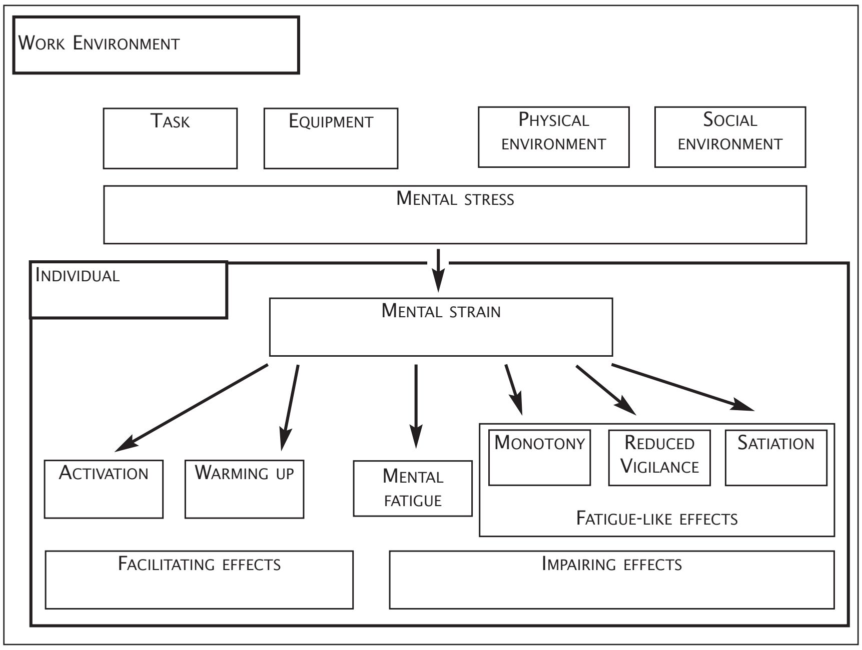
Although the general S-O-R (Stimulus-Organism-Response) concept of the stress - strain model had already been laid down in ISO 6385, a specification in the field of mental workload seemed more than appropriate because terms were (and still are) used in very inconsistent ways in this area. Whereas all kinds of conceptions of “stress” – stimulus-oriented (i.e. relating to stressors outside the individual), response-oriented (i.e. relating to stress reactions within the individual) or interaction-oriented (i.e. relating to the interactions and interdependencies between stressors and stress reactions) - can be found in the scientific literature, ISO 10075 uses the term *mental stress* for “the total of all assessable influences impinging upon a human being from external sources and affecting it mentally”, i.e. for the stimulus side. Restricting the term to external factors is based on considerations of what can be assessed objectively (e.g., by independent observers) and influenced by work design. There was a deliberate decision to omit possible sources of workload within the individual, since these would be difficult to assess or measure objectively and/or to be influenced by work system design or operation. It should be noted that the term *mental stress* as used in the standard therefore does not refer to any subjective, individual perceptions or evaluation of working conditions but only to the objectively assessable working conditions themselves.

The *internal response* of the organism to mental stress is described by the term *mental strain*, the "immediate effect of mental stress within the individual (not the long-term effect) depending on his/her individual habitual and actual preconditions, including individual coping styles". This formulation recognises that the same stimulus (stress) may lead to different responses (strain) in different individuals, depending on the individual's particular characteristics.

Mental strain will lead to facilitating and/or to impairing effects. Facilitating effects of mental strain in the individual are defined as "warming up" and "activation", impairing effects are "mental fatigue" and "fatigue-like states", i.e. "monotony", "satiation", and "reduced vigilance". All these are short-term effects of mental stress and strain within the individual, whereas long term effects, apart from a "practice effect", are not addressed in this standard, which is also true for (emotional) stress responses within the individual (or stress in colloquial language). This might seem a failing from a scientific point of view, but it is due to what could be achieved / agreed in standardisation at the time when the standard was being developed. This will most probably be changed in a future revision of the standard, especially with regard to stress responses, for which much empirical evidence is available to make it a serious, evidence-based concept to be dealt with in this standard. Figure 1 shows a model of the "stress - strain – consequences" conception of mental workload as laid down in ISO 10075: 1991.

One important thing to note (regardless of whether processes internal or external to the individual are concerned) is a clear distinction between "fatigue" and "fatigue-like" states, which can be distinguished by their antecedent conditions (and thus will require different design solutions for avoiding them, see Part 2) and their recovery processes. Whereas mental fatigue, i.e. a "temporary impairment of mental and physical functional efficiency, depending on the intensity, duration and temporal pattern of the preceding mental strain", requires recuperation time, recovery from fatigue-like effects, like monotony or reduced vigilance, can be achieved nearly instantaneously by changes in activity or environmental conditions.

Figure 1 **The stress-strain-effects model of ISO 10075**



Also notable is that the term "monotony" is reserved for the *internal* reaction within the individual, resulting from a specified pattern of mental workload. "Monotony", i.e. a "slowly developing state of reduced activation which may occur during long, uniform, repetitive tasks or activities, and which is mainly associated with drowsiness, tiredness, decrease and fluctuations in performance, reductions in adaptability and responsiveness, as well as an increase in variability of heart rate" is therefore used to describe the *effects* of a work situation within the individual, but not the characteristics of that work situation or work task.

Mental satiation, a concept fairly unfamiliar to the Anglo-American, but well documented in the European, literature, is defined as a "state of nervously unsettled, strongly emotional rejection of a repetitive task or situation in which the experience is of 'marking time' or 'not getting anywhere', with additional symptoms of anger, decreased performance, and/or feelings of tiredness, and a tendency to withdraw. Mental satiation in contrast to monotony and reduced vigilance is characterised by an unchanged or even increased activation level, coupled with a negative emotional quality".

The main reason for differentiating between these impairing consequences of mental stress and strain is their causation by different (external) working conditions which requires different solutions in the design of work systems and tasks. That is why Part 2 on design principles was so laid out as to present the design principles relevant for avoiding each of these different impairing consequences in different clauses. Hopefully, this will add clarity to future discussions on work design.

As well as defining the relevant terms, ISO 10075 describes the general conceptual model for the mental workload area, and provides examples for the elements of the model and the interrelationships described. It states very clearly that the term "stress" as used in this standard *has no negative connotations*, as in colloquial use, but is used in a *strictly neutral* way to describe the (observable and designable) stimulus side of a work system. This is why stress within the meaning of this standard can also have positive effects and not necessarily just negative ones. ISO 10075 should thus enable the designer (and other users of this standard from different disciplines) to understand what the concepts mean and how they are related to each other. It should also enable such users of the standard, including producers of other ergonomics standards, e.g., for software or equipment design, to understand that ergonomics has a much broader scope than just performance, and to make use of such concepts in specifying design requirements for system components, equipment or tools, or for the operation of work systems, even if an absolute measurement for mental workload or its effects is not available. ISO 10075 can thus be used to make clear that from an ergonomic perspective, it is not just performance that counts, but the effort, or strain, necessary to achieve it, together with the effects that this has on the individual. Evaluating work systems, products or tools, e.g. software, on the basis of performance criteria alone , and disregarding mental workload, is therefore clearly deficient from an ergonomic perspective.

3. ISO 10075-2:1996 Ergonomic principles related to mental workload - Part 2: Design principles

ISO 10075-2 provides *guidelines* for the *design* of work systems relating to mental workload. Although it is acknowledged that selection and training are also relevant for the resulting mental workload of operators in a work system (via influencing the operators' available resources for coping with the mental stress, see Part 1), these issues are not addressed in this standard (except for a clause requesting the designer to specify the necessary training to operate the system, i.e. as a design requirement). The standard is structured according to the definitions and concepts described in part 1, providing information on how mental workload is influenced by certain design characteristics and how these can be used to avoid or reduce possible impairing effects, i.e. mental fatigue, monotony, satiation, and reduced vigilance.

It should be clear, however, that the aim of the standard is *not to reduce mental workload (or stress) to the minimum possible*, as (erroneously?) called for by European Directives, but to optimise it (reducing stress to the minimum possible would make sense only if stress were negative or bad by definition, which it is not in the terminology of this ergonomics standard, see above.) Avoiding overload is just one aspect; avoiding underload is also important. What is really required is to avoid any kind of dysfunctional mental workload, and to provide for optimal mental workload which will avoid impairing effects and promote facilitating effects and the personal development of the workers. By introducing such general design principles the standard thus makes clear that it is not just about avoiding over- or underload on a single unidimensional concept (e.g., like activation, arousal or effort) but that there are *qualitative* differences in mental workload which have to be observed in the design of work systems.

The specific design guidelines are then arranged according to the effects they are intended to influence (i.e., guidelines concerning mental fatigue, monotony, reduced vigilance, and mental satiation) and the level of design (task, equipment, environment, and organization). They include aspects of influencing the resulting *quality* and *intensity* of the mental workload as well as its *duration* and/or *distribution* over time.

Guidelines relating to the intensity of the mental workload with regard to mental fatigue include aspects like ambiguity of task goals, presentation of information, dimensionality and dynamics of control movements, building up and making use of mental models, using decision support systems, compatibility problems, time pressure, etc. Guidelines concerning monotony deal with conditions known to increase monotony, e.g., repetitiveness, a narrow field of attentional requirements, monotonous environmental conditions, and how to avoid them. Similar guidelines are presented for satiation, e.g., avoiding structurally similar tasks by appropriate principles of task and/or job design. In order to avoid reduced vigilance, the standard states that the requirement for sustained attention in a narrowly focused field of attention, together with conditions known to decrease vigilance, e.g. low signal detectability, signal frequency, etc., shall be avoided as far as possible by appropriate design.

Since the effects of being exposed to this workload are dependent not just on the intensity of the workload (in all its qualitatively different aspects), but also on the temporal characteristics of the exposure, guidelines for the temporal organization of work are also given, e.g., on the duration of working hours, time off between successive shifts, shift work, breaks and rest pauses, as well as changes in task activities with different task demands or kinds of mental workload.

4. ISO/DIS 10075-3 Ergonomic principles related to mental workload - Part 3: Principles and requirements concerning methods for measuring and assessing mental workload

It would, of course, be valuable to have some standardised, easy to handle, reliable and valid diagnostic methods in order to assess mental stress, strain and their effects. The problem is, however, that no such generally accepted measurement methods or procedures exist (or probably ever will, since mental workload is not a unitary concept which can be measured by a simple indicator). Neither performance parameters nor psychophysiological parameters are unequivocal but have to be related to and interpreted in the conditions and context of measurement. Subjective measures (e.g., questionnaires, scaling procedures) are language and culture-dependent and cannot be standardised without cross-cultural research and adaptation, and of course they are subject to the subjects' reactivity, especially in field settings under real life conditions where the results of such measurements may lead to easily identifiable or potential consequences for the people involved. This makes subjective ratings somewhat problematic, especially under real-life conditions, even if they show adequate psychometric characteristics in the laboratory. This is commonly accepted in decisions about the ability to drive a vehicle after alcohol consumption, where such a decision based on the individual's own positive self-evaluation would not be acceptable, but some objective indication of blood alcohol concentration would be required. Subjective ratings in the area of mental workload therefore have to be treated with all necessary professional care and precautions, especially in situations where something might be at stake for the individual.

Another problem is whether all diagnostic methods could be standardised in a form that makes them easily applicable without specialised professional training. Evidence from a recent research project (Nachreiner *et al.*, 1998) indicates that this is not very probable. In this project, selected guidelines from part 2 were converted into separate checklists, one for use by ergonomics experts and one for practitioners from the health and safety departments of small and medium-sized companies. The results showed that whereas the experts were able to evaluate the design quality of work systems with regard to mental workload by using their checklists, practitioners experienced many problems in understanding and using the concepts represented in their checklist, even though the items were illustrated by examples and extensive descriptions. In fact, the practitioners' evaluations could not be regarded as valid assessments of the mental workload of the operators in these systems. This would mean that some methods at least would be restricted for use by professionals only. The question, however, is whether and how methods can be found or developed that are equally usable by non-experts or practitioners and yield acceptable, i.e. reliable and valid, results. This raises the question of how to evaluate or select appropriate diagnostic methods for a given purpose.

Bearing these problems in mind, together with the fact that mental workload is not a unitary concept for which no single best way of measurement can be found and standardised therefore, WG 2 decided not to standardise individual methods or instruments for the assessment or measurement of mental workload but to prepare a standard on *requirements for such methods or instruments*. This should assist the parties involved in measuring mental workload to choose the most appropriate methods for their specific purpose from those available, as well as helping them develop methods or instruments on the kind of information required on psychometric criteria to make such instruments suited for use on the shop floor. The aim was therefore to provide information on which to base a well-informed choice (or an evaluation) of a measurement approach most suited to the particular purpose at hand and to tell developers of such instruments what kind of information must be provided for this.

ISO/DIS 10075-3 is based on a two-dimensional model to categorise individual measurement approaches. The first dimension concerns the step in the stress - strain - effects process (see part 1). Measurement instruments / procedures must be specific about the intended domain of measurement, i.e. whether they intend to assess mental stress, mental strain or effects of mental strain, and this has to be demonstrated by empirical evidence.

The second dimension represents the quality of the measurement, categorised into three levels, from measurement at an orienting level through a screening level to precision measurements. This gives a two-dimensional matrix, object by precision of measurement, which allows for all kinds of combinations, e.g., high precision measurement of mental stress, low precision measurement of fatigue, etc. A third dimension, conceivable as layers of this matrix, is the measurement technique, ranging from job and task analysis through performance assessment and subjective scaling techniques to psychophysiological measurements. Psychophysiological measurements will most probably not be employed for orienting measurements and cannot be handled by non-experts, while subjective scaling techniques would seem less suited to assessing mental stress than for strain or the effects of strain within the individual, although such methods can be imagined on all levels of precision or measurement quality.

Measurement quality is defined in ISO/DIS 10075-3 via common psychometric criteria, i.e. objectivity, reliability, validity, sensitivity and diagnosticity. Objectivity means that the results of using an instrument should be independent of the people performing and interpreting the measurement. Reliability means that measurements yield replicable results. Validity means that an instrument measures what it intends to measure, e.g., stress if the intention is to measure stress and not strain. Sensitivity concerns the ability of an instrument to differentiate between different degrees of the object of measurement (e.g., whether a discrimination between extremes only or a fine grained discrimination is possible). Diagnosticity means that an instrument is specific for the intended purpose of measurement and not confounded by other aspects, e.g., providing indices of mental fatigue independent of effects of monotony, or a mixture of everything, including satisfaction.

Procedural and quantitative requirements have been formulated for these criteria. Quantitative requirements have been formulated for each level of precision for each criterion, so that an instrument may attain different levels at different criteria, e.g., high reliability but only medium sensitivity. So the potential user of an instrument, or parties involved in negotiations about mental workload in a work system, can decide which of the available instruments is most appropriate for their purposes. Another important point in the standard is the specification of procedural requirements, since validation has always been a problem with most instruments in the past, for example. The deficiencies of validation strategies where validity is claimed by comparison of a few extreme conditions either in intensity or duration, have long been well-known. It was therefore decided to specify in this standard what the minimal requirements are for an acceptable validation strategy, at least according to this international standard, and how objectivity, reliability, validity, sensitivity, and diagnosticity (which are defined in the standard) are to be demonstrated and documented. This should help the designer of measuring instruments, such as questionnaires or checklists, to select appropriate development strategies and to provide the necessary information. For potential users, it will offer the possibility to evaluate whether an instrument or technique has been properly designed and evaluated and can be used for the intended purpose.

The information to be provided by the designer is specified in documentation requirements, which include the above-mentioned psychometric criteria and their empirical basis, as well as the necessary professional background or training for potential users. In order to be able to evaluate whether not only a suitable instrument has been chosen but the specific measurement has been conducted according to the rules, documentation requirements are also specified for performing measurements in the field of mental workload.

In general then, this standard should help to improve measurement techniques and instruments, the selection and application of appropriate instruments, and the results of measurement in the field of mental workload, thereby contributing to a more rational treatment of this topic in the design and operation of work systems.

5. Future perspectives

It is hoped that ISO/DIS 10075-3 will successfully pass the voting in the near future, for which again support will be needed, and can be promoted to an International and a European Standard as soon as possible. For Part 3, combined voting at ISO and CEN has been agreed, so that now the official French and German versions have been prepared for the voting in CEN. As far as can be seen, there appear to be no major political obstacles at the moment, since the standard is on requirements for measuring instruments and not on the instruments themselves; and does not specify which precision level has to be used. This is clearly a matter for negotiation among the parties involved and so was deliberately omitted from the standard.

Since all standards in the ISO 10075 series cover material with which many users may be unfamiliar, it was decided within WG2 to produce a less normative document (e.g., a Technical Report) to explain the terms, terminology, concepts and specifications of the standard in more detail, to make it more accessible to and usable by non-experts. For this reason, feedback on problems with using and handling the standards would be welcome, as well as co-operation in the preparation of this document.

Another potential problem is the ongoing revision of ISO 10075-1, since some of the suggested changes in this part might necessitate changes in parts 2 and 3, and the revision of ISO 10075 is intended to take account of the ongoing revision of ISO 6385. Since all parts of ISO 10075 have been developed in close co-ordination and are based on the same basic model and concepts, changes in part 1 (general terms and definitions) will inevitably lead to changes in parts 2 and 3; e.g., taking account of *stress reactions* in the individual (coupled with increased activation and feelings of threat or fear) that are commonly and colloquially called “stress”, or long-term effects of mental workload, e.g., burnout. It is hoped that WG 2 will be able to solve these problems in the near future; however, support and participation by more experts and more member bodies would be greatly appreciated, especially from the social partners, because the social and political implications of these standards have become quite clear in the meantime. A broader and more representative participation, including employer and especially employee representatives - which is quite low at present -, in the development and revision of the standards could help to improve the results, make them more applicable by tailoring them more closely to shop floor requirements, and reduce the mental workload of the members of the working group responsible for developing international standards on mental workload.

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The European guidance on work-related stress and the international standards on mental workload – Complementary aspects and differences

By Lennart Levi *

1. The European Commission's Guidance

In 1997, the Advisory Committee for Safety, Hygiene and Health at Work adopted the Ad Hoc Group Opinion on stress, calling for the Commission to draw up a voluntary guidance document. In 2000, the European Commission published its *Guidance on work-related stress – Spice of life or kiss of death ?*[1].

1. Levi, L and I, *Guidance on Work-Related Stress. Spice of Life, or Kiss of Death ?* Luxembourg, Office for Official Publications of the European Communities, 2000. It can be found in : http://www.europa.eu.int/comm/employment_social/h&s/publicat/pubintro_en.htm.

1.1. What is stress ?

According to the Commission Guidance, *stress* consists of a pattern of "stone-age" reactions preparing the human organism for fight or flight (that is, for physical activity) in response to *stressors*, i.e., demands and influences that tax the organism's adaptational capacity. Stress comprises the common denominators in an organism's adaptational reaction pattern to a variety of such influences and demands. In particular :

> "Stress is a pattern of emotional, cognitive, behavioural and physiological reactions to adverse and noxious aspects of work content, work organization and work environment. It is a state characterized by high levels of arousal and distress and often by feelings of not coping."

1.2. Can work-related stress be prevented ?

The Guidance argues that there is a need, to identify work-related stressors, stress reactions, and stress-related ill health. There are several reasons for doing this : stress is a problem both for workers and their work organisation, and for society; work stress problems are on the increase; there is a legal obligation

* Karolinska institutet, Stockholm, Sweden

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under the EU Health and Safety Framework Directive, and many of the stressors and consequences are avoidable and can be adjusted by all three labour market parties if they act together in their own and mutual interests.

The EU Framework Directive gives employers a "duty to ensure the safety and health of workers in every aspect related to the work". The Directive's principles of prevention include "avoiding risks", "combating the risks at source", and "adapting the work to the individual". The Directive also places a duty on employers to develop "a coherent overall prevention policy". The European Commission's Guidance aims to provide a basis for such endeavours.

Based on surveillance at individual workplaces and monitoring at national and regional levels, work-related stress should be prevented or counteracted by job-redesign (e.g., by empowering the employees, and avoiding both over- and underload), by improving social support, and by providing reasonable reward for the effort invested by workers, as integral parts of the overall management system. And, of course, by adjusting work-related physical, chemical and psychosocial settings to the workers' abilities, needs and reasonable expectations - all in line with the requirements of the EU Framework Directive and Article 152 of the Treaty of Amsterdam which requires that "a high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities".

1.3. Tools to prevent stress

The way to identify the instances, causes and consequences of work-related stress is to *monitor* job content, working conditions, terms of employment, social relations at work, health, wellbeing and productivity. The CEC Guidance provides many references to checklists and questionnaires to enable stakeholders to do this.

Once the labour market parties have identified the "sore point", action can be taken to alleviate the problem, i.e., to improve stress-inducing conditions in the workplaces. The Guidance argues that much of this can be accomplished through organisational changes, e.g., by :

- Allowing adequate time for the worker to perform his or her work satisfactorily.
- Providing the worker with a clear job description.
- Rewarding the worker for good job performance.
- Providing ways for the worker to voice complaints and have them considered seriously and swiftly.
- Harmonising the worker's responsibility and authority.
- Clarifying the work organisation's goals and values and adapting them to the worker's own goals and values, whenever possible.
- Promoting workers' control, and pride, over the end product of their work.
- Promoting tolerance, security and justice at the workplace.
- Eliminating harmful physical exposures.
- Identifying failures, successes, and their causes and consequences in previous and future health action at the workplace; learning how to avoid the failures and how to promote the successes, for a step-by-step improvement of occupational environment and health (Systematic work environment management, see below).

On a company or national level, all three labour market parties may wish to consider organisational improvements to prevent work-related stress and ill health, with regard to :

- *Work schedule*. Design work schedules to avoid conflict with demands and responsibilities unrelated to the job. Schedules for rotating shifts should be stable and predictable, with rotation in a forward (morning-afternoon-night) direction.
- *Participation/control*. Allow workers to take part in decisions or actions affecting their jobs.
- *Workload*. Ensure assignments are compatible with the capabilities and resources of the worker, and allow for recovery from especially demanding physical or mental tasks.
- *Content*. Design tasks to provide meaning, stimulation, a sense of completeness, and an opportunity to use skills.
- *Roles*. Define work roles and responsibilities clearly.
- *Social environment*. Provide opportunities for social interaction,

including emotional and social support and help between fellow workers.
- *Future.* Avoid ambiguity in matters of job security and career development; promote life-long learning and employability.

1.4. Systematic work environment management

The Guidance points out that actions to reduce noxious work-related stress need not be complicated, time consuming, or prohibitively expensive. One of the most common-sense, down-to-earth and low-cost approaches is known as *Systematic work environment management*.

It is a self-regulatory process, carried out in close collaboration between stakeholders. It can be coordinated by, e.g., an in-house occupational health service or a labour inspector, or by an occupational or public health nurse, social worker, physio-therapist, or personnel administrator.

Its first step is to *identify* the incidence, prevalence, severity and trends of work-related stressor exposures and their causes and health consequences, e.g., by making use of some of the survey instruments listed in the Commission Guidance.

In a second step, the characteristics of such exposures as reflected in the content, organisation and conditions of work are analysed in relation to the outcomes found. Are they likely to be *necessary*, or *sufficient*, or *contributory* in causing work-stress and related ill health ? Are they susceptible to change ? Are such changes acceptable to relevant stakeholders ?

In a third step, the stakeholders may design and implement an integrated *package of interventions* in order to prevent work-related stress and to promote both wellbeing and productivity, preferably by combining top-down and bottom-up approaches.

The short- and long-term *outcomes* of such interventions need then to be *evaluated*, in terms of (a) stressor exposures, (b) stress reactions, (c) incidence and prevalence of ill health, (d) indicators of wellbeing, and (e) productivity with regard to the quality and quantity of goods or services. Also to be considered are (f) the costs and benefits in economic terms.

If the interventions produce no or negative effects in one or more respects, stakeholders may wish to reconsider what should be done, how, when, by whom and for whom. If, on the other hand, outcomes are generally positive, they may wish to continue or expand their endeavours along similar lines. It simply means systematic *learning from experience*. If they do so over a longer perspective, the workplace becomes an example of *organisational learning*.

Experiences with such interventions are generally positive, not only for the employees and in terms of stress, health and well-being, but also for the function and success of work organisations, and for the community. If conducted as proposed, they are likely to create a *win-win-win* situation for all concerned.

2. The European standards related to mental workload

The international series of standards ISO 10075, Part 1[2] and 2[3] related to mental workload were adopted and published as *European Standards* by CEN in July and March 2000. In so doing, the members of CEN have given this Standard the status of a national standard "as is". Although the European standards are not mandatory they do provide a technical basis on the subject of mental workload. The mandated standard under the Machinery Directive - EN 614-1 on *Ergonomic principles for machinery design* - is currently under revision. Should the EN ISO 10075 series be put in the normative references, then they will become part of the standard. They would then confer a presumption of conformity on mental workload issues, although EN ISO 10075 focuses on more than just machinery design. This prospect adds a certain weight to the EN ISO 10075 series and its approach to mental workload and stress.

2. EN ISO 10075-1:2000 Ergonomic principles related to mental - workload - Part 1: General terms and definitions.

3. EN ISO 10075-2:2000 Ergonomic principles related to mental workload - Part 2: Design principles.

In this Standard, *mental stress* is defined as "the total of all assessable influences impinging upon a human being from external sources and affecting it mentally".

Mental strain is correspondingly defined as "the immediate effect of mental stress within the individual (*not* the long-term effect) depending on his/her individual habitual and actual preconditions, including individual coping styles".

The Standard lists some "facilitating" and "impairing" (short-term) effects of mental strain. The former include "warming-up effects" and "activation", whereas the latter comprise "mental fatigue", and "fatigue-like states" such as "monotony", "reduced vigilance" and "mental satiation".

The Standard makes the point that the consequences of mental strain include yet further consequences, e.g., boredom and feelings of being overloaded, which are, however, not dealt with in the Standard, "due to large individual variation, or to as yet inconclusive results of research". The same is said to apply to "possibly unfavourable long-term effects of repeated exposure to mental strain being either too high or too low".

In its "general design principles", the Standard emphasizes the need to fit the work system to the user, and in doing this, to utilize their experiences and competencies, for instance by using participatory methods.

These principles should be applied in order to influence (a) the intensity of the workload, and (b) the duration of the exposure to the workload. Personal factors, like abilities, performance capacities, and motivation will influence the resulting workload.

The work system design accordingly starts with a function analysis of the system, followed by function allocation among operators and machines, and task analysis, and results in task design and allocation to the operator.

The Standard points out that mental workload is not a one-dimensional concept but has different qualitative aspects leading to different qualitative effects.

The Standard provides guidelines concerning fatigue, monotony, reduced vigilance, and satiation. It presents their determinants in considerable detail and exemplifies them.

3. A comparison between the two approaches

3.1. The stress-stressor-strain concepts

The European Standard defines “mental stress” as a stimulus – generally in line with the corresponding definition in physics, as “a force that tends to strain or deform a body”. The Guidance has chosen the current psychosociobiological stress concept originally introduced by Selye (1936), comprising the common denominators in an organism’s adaptational reaction pattern to a variety of influences and demands.

According to the European Standard, stress (= the stimulus) induced “mental strain” (= the reaction). The non-specific aspects of the latter are what the Guidance refers to as “stress”.

The European Standard’s “stress” concept equals the Guidance’s concept of “stressor”.

It is, of course, important to point out this fundamental difference between the two sets of definitions, to avoid confusion.

3.2. Negative, positive, or neutral connotations

The European Standard emphasizes that its stress concept is regarded as neither intrinsically negative nor positive. Depending on the context it can be both or neither. Similarly, the Guidance indicates that stress can be positive (“the spice of life”) or negative (“a kiss of death”), depending on the context and on interindividual variation.

3.3. Unfavourable long-term effects ?

The European Standard excludes consideration of possible negative long-term effects because of “the yet inconclusive results of research”. The Guidance, prepared almost a decade later, takes the opposite view and presents a wide variety of negative (health) effects of long-term stressor exposures, documenting its claims. The latter evaluation is also in line with the World

Health Organization's formulation that "mental health problems and stress-related disorders are the biggest overall cause of early death in Europe".

As can be easily seen, these two approaches are based on different but related paradigms. The European Commission's Guidance has its roots in workers' protection, stress medicine and psychology, and in an ecological or systems approach. The European Standard is based on ergonomics, an applied science of equipment and work process design also intended to improve the overall system performance by reducing operator fatigue and discomfort, as well as ensuring their health, safety and wellbeing.

The Guidance was prepared with the awareness that "one size does not fit all". It is an hors-d'oeuvre, a "pick and mix" selection from which all stakeholders are invited to choose the combination of interventions considered to be optimal in their specific setting, for subsequent evaluation.

It chimes with the European Framework Directive and is aimed at preventing work-related ill health and promoting wellbeing and productivity.

The Standard is more precise in its indications of what to include and what to promote and how. It refers to all kinds of human work activity with the explicit aim to "fit the work system to the user". Although unstated, it leaves the distinct impression that productivity (and not health and wellbeing) should be considered as the primary outcome.

On many points, the Guidance and the Standard overlap, both in terms of objectives and with regard to the means by which these objectives should be achieved.

That said, the two initiatives do represent important bases for the promotion of high levels of occupational and public health, and good quality of life.

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