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New developments in standardisation in the past 15 years — product versus process related standards

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Abstract
This paper gives some background information on standards and standards bodies, then describes the development of process-related standards and finally explains the links between European/international standardisation and European Community legislation. © 2001 Published by Elsevier Science Ltd. All rights reserved.

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1. Standards and standards bodies

1.1. What are standards?
Standards are documents containing technical specifications or other precise criteria to be used consistently as rules, guidelines, or definitions of characteristics, to ensure that materials, products, processes and services are fit for their purpose. They contribute to making life simpler, and to increasing the reliability and effectiveness of the goods and services.

1.2. Who makes standards?
Standards are the result of voluntary agreements between all interested parties. They are developed at national, European or international level. Examples for national standards bodies are: Association française de normalisation (AFNOR), American National Standards Institute (ANSI), British Standards Institution (BSI), China State Bureau of Quality and Technical Supervision (CSBTS), Deutsches Institut für Normung (DIN) or Standardiseringsen i Sverige (SIS).
1.2.1. European standards bodies

In Europe, there are three standards bodies: the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) and the European Telecommunications Standards Institute (ETSI). Their mission is to develop and achieve a coherent set of voluntary standards as a basis to a Single European Market/European Economic Area without internal frontiers for goods and services inside Europe. Their work is carried out in conjunction with world-wide bodies and the national standards bodies in Europe.

1.2.2. International standards bodies

International standardisation began in the electrotechnical field: the International Electrotechnical Commission (IEC) was created in 1906. Following the Second World War, the International Organisation for Standardisation (ISO) was created in 1947 and the first ISO standard was published in 1951. ISO is a world-wide federation of national standards bodies from some 130 countries, one from each country. It is a non-governmental organisation. The mission of ISO is to promote the development of Standardisation and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing co-operation in the spheres of intellectual, scientific, technological and economic activity.

1.3. Why are international standards needed?

The existence of non-harmonised standards for similar technologies in different countries or regions can contribute to so-called “technical barriers to trade”. Export-minded industries have long sensed the need to agree on supranational standards to help rationalise the international trading process. Harmonisation diminishes trade barriers, promotes safety, allows interoperability of products, systems and services, and promotes common technical understanding.

2. From product to process related standards

2.1. Background

Until the mid-1980s, standards were mostly product-related and highly specific. Then, in 1987, came ISO 9000, followed nearly 10 years later by ISO 14000, which have brought ISO to the attention of a much wider community. These two series of standards are very different from the majority of highly specific standards. ISO 9000 and ISO 14000 are practical tools to assist users in business and government to assure the quality of their products and services, and to manage the impact of their activities on the environment. Like all standards, their use is voluntary. Both series of standards are known as generic management system standards. Generic means that the same standards can be applied to any organisation, large or small, whatever its product — including whether its “product” is actually a service — in any sector of activity, and whether it is a business enterprise or a public authority. Management
system refers to what the organisation does to manage its processes or activities. Management system standards provide the organisation with a model to follow in setting up and operating the management system.

2.2. *The ISO 9000 series of standards*

1. The ISO 9000 series of standards describe different kinds of quality assurance systems. There are three different quality assurance standards:
2. ISO 9001 sets out the requirements for an organisation whose business processes range all the way from design and development, to production, installation and servicing;
3. ISO 9002 does not include the design control requirements of ISO 9001, and is therefore appropriate for an organisation which does not carry out design and development, otherwise, its requirements are identical;
4. ISO 9003 is the appropriate standard for an organisation whose business processes do not include design control, process control, purchasing or servicing, and which basically uses inspection and testing to ensure that final products and services meet specified requirements.

There is no difference of quality ranking between these three standards.

2.3. *The ISO 14000 series of standards*

ISO 14000 grew out of ISO’s commitment to support the objective of “sustainable development” discussed at the United Nations Conference on Environment and Development, in Rio de Janeiro, in 1992. The ISO 14000 series of standards began in 1996 with the publication of ISO 14001, the generic standard for Environmental Management Systems (EMS). An EMS provides a framework for an organisation to manage the impact of its activities on the environment. Since 1996, further standards have followed on life cycle assessment (14040 series) environmental labelling (14020 series) and performance evaluation (14030 series) all of which represent tools to help the organisation realize its environmental policy, objectives and targets. The ISO 14000 standards differ from those of the ISO 9000 series by approaching management from a “Plan, Do, Check, Act” model as opposed to the process based model of ISO 9000. However, similar to the ISO 9000 series, they are intended to be applicable to all sectors and all sizes of business.

3. The links between European/international standards and European Community legislation

3.1. *Background*

Although the use of standards is voluntary, their application has often been rendered mandatory by incorporating them or referring back to them in national and
European Community legislation. However, legislation containing a multitude of detailed technical specifications has become very vulnerable to being overtaken by technical progress and thus has to be regularly adapted to technical progress. This means going through onerous legislative processes. This has changed with the introduction of the “New Approach” to technical harmonisation and standardisation followed by the “Global Approach” to testing and certification. Both approaches aim at underlining the importance of European and international standardisation by “transferring tasks” from the legislator to the standards bodies. Recently, this trend has also found its way into voluntary environmental instruments, such as the “Eco-Management and Audit Scheme” (EMAS).

3.2. The “New Approach” to technical harmonisation and standardisation

The “New Approach”, defined in a Council Resolution of May 1985, represents an innovative way of technical harmonisation. It introduces a clear separation of responsibilities between the EU legislator and the European standards bodies CEN, CENELEC and ETSI in the legal framework allowing for the free movement of goods. EU technical harmonisation Directives define the “essential requirements”, e.g. protection of health and safety, that goods must meet when they are placed on the market. The European standards bodies have the task of drawing up the corresponding technical specifications meeting the essential requirements of the Directives, compliance with which will provide a presumption of conformity with the essential requirements. Such specifications are referred to as “harmonised standards”. “Harmonised standards” are European standards, adopted by CEN, CENELEC or ETSI, following a mandate issued by the European Commission after consultation of Member States. They are developed through an open and transparent process, built on consensus between all interested parties. Compliance with harmonised standards, of which the references have been published in the Official Journal of the EU and which have been transposed into national standards, provides presumption of conformity to the corresponding essential requirements of the EU technical harmonisation Directives. Compliance with harmonised standards remains voluntary, and manufacturers are free to choose any other technical solution that provides compliance with the essential requirements.

3.3. The “Global Approach” to certification and testing

The “New Approach” was complemented by the “Global Approach” to certification and testing which lead to the adoption of the so-called “modules” Decision in 1994. While the “New Approach” only covers the relationship between the essential (technical) requirements of the harmonisation Directives on the one hand and the harmonised European standards on the other, the “Global Approach” concerns conformity assessment, i.e. the procedure(s) described in the Directives that an industrial operator must apply in order to prove the conformity of his product with the requirements of the Directives. The above-mentioned Council Decision led to the introduction of modules for the different phases of conformity assessment (design
and production). This means that a harmonised framework of procedures was created, from which one or more procedure could be chosen whenever a technical harmonisation Directive had to be elaborated. Standards of the ISO 9000 series were incorporated into the modules concept. This aimed at allowing industrial operators that have quality assurance systems according to the ISO 9000 series implemented in their companies to use these systems — after certification by an appointed body — to prove that the conformity assessment of their product has been carried out in compliance with the technical harmonisation Directives.

3.4. The Eco-Management and Audit System (EMAS)

In the light of experience gained with regulatory approaches during the 20 years of Community environmental policy, the traditional prescriptive “command and control” approach was complemented by a self-regulatory approach controlled by third parties. The EMAS Regulation establishes a voluntary environmental management scheme, based on harmonised lines and principles throughout the EU, open to companies in the industrial sector operating in the EU and the European Economic Area. The Regulation came into force in July 1993. The scheme has been open for participation by companies since April 1995. Its aim is to promote continuous environmental performance improvements of industrial activities by committing sites to evaluate and improve their own environmental performance and provide relevant information to the public. The scheme does not replace existing Community or national environmental legislation or technical standards nor does it, in any way, remove a company’s responsibility to fulfil all its legal obligations under such legislation or standards. Although entering into force in advance of the ISO 14000 series of standards, the similarities are great and Commission Decisions of 1997 recognised the use of ISO 14001 within the EMAS regulation. The revision of the EMAS Regulation anticipated for the 4th quarter of the year 2000 goes further than this and incorporates ISO 14001 into the regulation as “the management system” to be used within EMAS, thus providing greater recognition for the international standard.

4. Final remarks

Standardisation as well as the regulation of technical risks is increasingly being undertaken at European or international level. The European legislator limits its role to the affirmation of overall objectives, and leaves it to the economic players to draw up the technical procedures and standards to specify in detail the ways and means of attaining them.

The Seveso II Directive aims at the prevention of major industrial accidents and the limitation of their consequences to man and the environment to ensure high levels of protection throughout the EU in a consistent and effective way. Industrial operators that use large amounts of dangerous substances must demonstrate that they have assessed the risks and are managing them. However, no corresponding procedures are contained in the Directive. As a result of difference of cultures in the
Member States of the EU, a variety of such procedures is currently in use, employing different terminologies and underlying philosophies, making cross-comparison of results and coherent decision-making difficult.

As has been described earlier, a decisive value is put on standards in EU legislation. Process-related generic standards have already been developed in the areas of quality and environmental management. The development of a generic standard for risk-based decision making would certainly represent a major step forward in achieving a common language in risk assessment across different technical areas and sectors. It would not only be of great value for risk assessors and risk decision-makers in both, industry as well as in public authorities but would also contribute to international harmonisation in this field. This will hopefully contribute to reducing technological hazards and to protecting our health and our environment.

5. Information available on the Internet

Joint Research Centre (JRC) of the European Commission http://www.jrc.it/
Major Accident Hazards Bureau (MAHB) http://mahbsrv.jrc.it/
Association française de normalisation (AFNOR) http://www.afnor.fr/
American National Standards Institute (ANSI) http://www.ansi.org/
British Standards Institution (BSI) http://www.bsi.org.uk/
China State Bureau of Quality and Technical Supervision (CSBTS) http://www.csbts.cn.net/
Deutsches Institut für Normung (DIN) http://www.din.de/
Standardiseringen i Sverige (SIS) http://www.sis.se/
European Committee for Standardisation (CEN) http://www.cenorm.be/
European Committee for Electrotechnical Standardisation (CENELEC) http://www.cenelec.be/
European Telecommunications Standards Institute (ETSI) http://www.etsi.org/
International Organisation for Standardisation (ISO) http://www.iso.ch/
ISO 9000 and ISO 14000 series of standards http://www.iso.ch/9000e/9k14ke.htm
“Eco-Management and Audit Scheme” (EMAS) http://www.europa.eu.int/comm/environment/emas/index.htm