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The IPTS REPORT

EDITED BY THE INSTITUTE FOR PROSPECTIVE TECHNOLOGICAL STUDIES (IPTS)
AND ISSUED IN COOPERATION WITH THE EUROPEAN S&T OBSERVATORY NETWORK

SPECIAL ISSUE: STANDARDIZATION AND RTD

EUROPEAN COMMISSION
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At the same time, the 5FP encourages a much stronger interaction among the research communities and the working committees of the European standardisation bodies to ensure that standards developed are appropriate and timely. In that respect, the Joint Research Centre (JRC) has recently signed a co-operation agreement with CEN/STAR, one of the European standards issuing bodies, to contribute to this debate and promote the transfer of its research results towards standardisation. As an active contribution to the implementation of this agreement, I have instructed the IPTS to dedicate this issue of the "The IPTS Report" to Standardisation and RTD, thus emphasizing my personal commitment, and that of the European Commission, to improve European Competitiveness and Growth.

Edresson

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SPECIAL ISSUE: STANDARDIZATION AND RTD

EDITORIAL

Ioannis Maghiros*, *IPTS*

Standards promote a common technical "language" for industry, confidence in products and services to consumers and can help in both creating new markets and opening up existing ones. The standardization process helps avoid future interoperability problems, by suppressing proprietary solutions at an early stage and is thus crucial in enhancing technological infrastructure. On the other hand standardization is extremely costly and should therefore take into account social needs so as to ensure common social benefits.

The European standardization system, which runs on strong national legs, is among the most developed in the world. Globalization is progressively reducing the scope for national standards and increasing that for international ones (e.g. by the International Organization for Standardization –ISO, the International Telecommunications Union - ITU). Nevertheless, the EU and the U.S. have different approaches and systems, which makes harmonization difficult (a subject under discussion by the World Trade Organization within the Transatlantic Dialogue on Technical Barriers to Trade). Standardization bodies are currently offering new types of products including codes of practice, technical specifications and workshop agreements. Yet, we are still far from the ideal situation where industry attains a "one standard, one test, recognized everywhere" situation as well as one in which the needs of SMEs, the motor of European economy, are given detailed consideration.

The relation between legislation and standardization is also evolving. A new approach on "legislation" was adopted in 1985 by the European Council of Ministers. New directives describe levels of performance rather than particular means of achieving them, thus enabling constant technological evolution and allowing standardization bodies to do their job. The new approach has also introduced the principle of "presumption of conformity with essential requirements". This speeds up the market accessing prospects in cases where public interests are not jeopardized.

In the future, standardization will not only have to cope with a variety of new products in both new and traditional sectors, but also to make inroads into the services sector, which is taking on increasing economic importance and is in need of a carefully defined legal framework. The Global Information Society and Electronic Commerce raise issues where, fast-technological development, standardization and regulation boundaries are becoming blurred, raising issues of appropriateness of existing instruments and doubts on human issues to be protected (privacy). Furthermore, a global legal framework for trade policy is desirable, which takes a broader view on the complex factors influencing international trade, e. g. R&D, metrology, standards, certification, Intellectual Property Rights (IPR).

However, an important aspect of standards is that once adopted, they can be very difficult to change because of their highly distributed nature and the consequent need for broad-range, costly alterations of user behaviour and infrastructure. Therefore standards development is another aspect of technology design which requires

careful investigation of its foreseen socio-economic implications to address social, legal and policy concerns. Scientific Assessment studies could lead to appropriate R&D activities taking place, enabling the development of elaborate testing and measurement tools as well as allowing the time-frame necessary to achieve consensus among all actors involved.

European research is playing a pivotal role in this respect by aiding in the preparation of new standards and also by involving all actors concerned (industry, R&D Labs and 'users'). The increasing number of application fields as well as the number of new standards required - mainly as a result of rapid technological development- is also making the need for increased R&D activities in developing specific measurement and testing systems more prominent. Advanced Instrumentation technologies are rapidly developing to aid in the manufacture of new measuring and testing equipment. There is a need for more targeted research and co-operation both before and during the standardization process to define priority standards. Quality certification is yet another field of growing R&D co-operation, where publicly accredited laboratories perform measurements and verifications required to certify that companies respect quality standards (i.e. that there be no lowering of standards due to intensified competition).

In November 1998, the Joint Research Centre Directorate-General (DG-JRC) of the European Commission signed a co-operation agreement with CEN, (European Committee for Standardization) handled in CEN by the STAR action group, the CEN horizontal body responsible for research and standardization, to contribute to this debate. This special issue of the IPTS Report is a product of this co-operation agreement. As well as presenting recent standardization concerns and their policy implications it seeks to emphasize the transfer of selected longer term RTD research results into standardization and the role of the JRC in this process.

In the prologue the Secretary General of CEN, Mr. Hongler, describes the functioning of CEN, its mandate and its reaction to the world of fast-developing technologies and policy requirements. Continuing with the introduction Mr. Vinard, chairman of the CEN Action Group STAR discusses the role of STAR and its efforts to address coordination of co-normative research problems. He also raises the issue of better exploitation of the results of pre-normative research, calling for a synergy between R&D and European Standardization efforts. In the first article of this issue, Dr. Saraiva Martins of the Directorate-General for Science, Technological Research and Development (DG-XII) presents the European Commission **standardization funding mechanism** plans within the Fifth Framework Programme, which has a clear orientation towards "user" needs and a strategically driven selection of R&D topics.

Dr. A. Wallard of the National Physical Laboratory (NPL, UK) addresses the need for a wider set of reliable and broadly accepted **measurement standards** and places emphasis on their potential impact on trade such as between the EU and the U.S. He suggests that it is only

through stronger R&D cooperation and related regulatory measures (dealing with metrological differences between countries), that we may overcome existing technical trade barriers. In the third article, Professor Kristoffersen, M.D., of the University of Lund, describes the case of developing standards on the **quality of genetic testing** at a European level. It is argued that a harmonization of regulations and standards is desirable to ensure equal access to genetic testing services in Europe in view of their far reaching ethical, legal and social consequences.

The Director of the German Standards Institute (DIN), Dr.-Ing T. Bahke, focuses on the need to identify a more efficient standardization system in those cases where complex systems and rapid innovation are involved. He suggests that **R&D phase standardization** while not replacing traditional standardization could aid in producing better standards. The fifth article centres its attention at the role of **reference methods and materials** for standardization. The IRMM institute of the JRC in Geel, presents its European policy support activities through the production, certification and validation of reference materials and methods. The sixth article presents the activities of the Structural Mechanics Unit of the ISIS institute of the JRC in Ispra in support of **uniform European design codes** for civil engineering structures.

Finally, Dr. A. Watson-Brown of the Directorate-General for Telecommunications, Markets, Technologies - Innovation and Exploitation of Research (DG-XIII), presents a **market-led model of pre-standardizing** based on bringing together actors with different business models early on in the process, and draws conclusions that redefine the relationship between research, standardization and regulation in the audiovisual sector.

* The author would like to acknowledge the valuable contribution of G. Carrati, to this editorial. G. Carrati is Advisor in charge of Relations with Community Policies with the Programmes Directorate of the JRC in Brussels.

Standardization in Europe

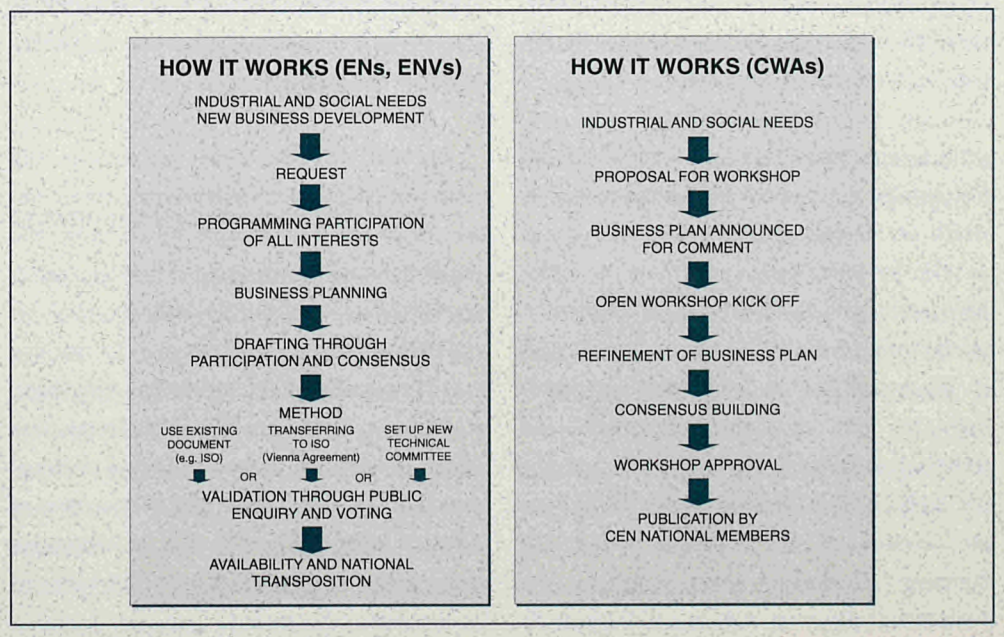
Georg Hongler, *Secretary General of CEN (European Committee for Standardization)*

Introduction

Standards create solutions to matters of safety, interoperability, management and common technical understanding. Engineers and designers would simply be lost without standards ranging from those for nuts and bolts to complex assemblies like pressure equipment. Once the concern only of engineers, standardization is now on the international political agenda. *Incompatible* standards are the subject of discussions in trade negotiations. The maintenance of trade barriers through the use of national standards and restrictive legislation are seen as unacceptable. On the other hand, *common* standards allow for greater, but fair, competition. They benefit customers and suppliers through increased sales and lower prices.

With the advent in Europe of the Single Market and the propulsion of its ideals into Eastern Europe, CEN, the European Committee for Standardization, has now become the largest regional standards body in the world. Moreover, it has proven that it is capable of delivering the standards which support the 'new approach' to technical harmonization in Europe. Certainly this often happens more slowly than desired but it must always be remembered that this 'new approach' really was *new* and all parties had to work in a different way in a context which in effect is deregulation. This means that without being laws themselves standards must have the legitimacy, quality, and acceptance of regulations.

Figure 1. European Standardization Path



CEN's objectives and future challenges

Emphasis must be placed on the way CEN works and the justification for the mandates entrusted to it. CEN is open, through a powerful network of members, to all representative interests. It works by *consensus*, which does not mean unanimity, but drafting the best possible specifications or methods of test achievable within a reasonable time-scale; the 'state of the art' is explicitly recognized in European Union legislation referring to safety. All draft standards are offered for a six-month period of public inquiry in which anybody in any part of the world, through their national standards body, may comment on the drafts.

Finally, standards are subjected to a formal vote. The vote is in fact an *obligation* on our Members to accept European Standards as national standards and withdraw all conflicting standards. This creates a consistent set of standards Europe-wide. Furthermore, this mechanism means that - in the context of the 'Vienna Agreement' between CEN and ISO (the International Organization for Standardization) - global standards adopted by ISO make up 40 % of CEN's portfolio and hence, necessarily, national standards. Global standards are always the first choice, provided they are suitable.

In Europe itself CEN's legitimacy is founded first upon the status of its National Members, all of which are formally recognized in one way or another by their States, and many of which have nearly one hundred years of experience. In the context of the European Union, CEN is recognized as a 'competent' standards body by the directive for standards and technical regulations (98/34/EC, (superseding 83/189/EEC)). This directive, legally binding on the countries of the European Union, the European Economic Area, together with Switzerland, allows for mandates to be given by administrations of the Member States to proceed to European standardization and stop all national work. Following the adoption of the directive in 1983, the Council defined the 'new approach' to standards in 1985. This followed frustration and slow progress, as at that time the Community (EEC) grappled with the technical annexes to directives, which required unanimity. The new doctrine defines the 'essential requirements', principally but not only in the domain of safety, leaving the technical details to the standardizers drawing on their experience at national level.

'Good' standards, by concentrating on performance characteristics rather than being prescriptive design criteria, state the values to be achieved. As an example, a standard for a protective helmet states the impact and penetrative forces it must resist. Any material or design that satisfies these requirements will be acceptable. So the designer knows the 'benchmark' which the national labour inspection authorities will find acceptable, this benchmark in turn being derived from the law-making and consultative procedures put in place by the Union treaties. As well as performance characteristics for safety and reliability, standards are also needed for interfaces between components or systems from different suppliers.

Recognizing that new technologies, in particular information technologies, move fast and that CEN is challenged by consortia and other industrial fora, the *Information Society Standardization System* (CEN/ISSS) has been set up. Its workshops are open platforms for reaching initial consensus. *CEN Workshop Agreements* (CWAs) give a fast route to acceptable solutions which can later be further developed as formal standards. In a first phase the development of CWAs is being managed by ISSS for information technologies; in a second phase CWAs will also be applied to other sectors.

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Linking R&D to Standardization: Getting more from the results of industrial research

Daniel Vinard, *Chairman of the CEN BT/AG "STAR"*

Introduction

European Industry relies on the **exploitation** of the results of its research. The synergy between research and standardization is an essential ingredient in getting full commercial benefit from its results. This synergy enables the market to be structured so as to accept the technologies and products, and allows researchers and standardizers to plan their actions and implement their projects.

As highlighted in the "Green Paper on Innovation" standardization is a vector of innovation, as it allows the introduction of the products of innovation onto the European Market in an organized and harmonized way. In this context, the mission of CEN/STAR is to strengthen the links between research and standardization activities; in particular to draft European Standards on **the solid factual bases** produced by research.

Standardization and Research Links

Standardization and R&D are inter-dependent, as standards must be anchored on factual and reliable data. The technology necessary for the development of a new standard may be created by a specific research project or may arise as a spin-off from research, innovation or development not directly linked to the preparation of a standard. Moreover, research leading to the development of new products or processes generally benefits from early knowledge of relevant standards and the subsequent value and marketability of the new product may be enhanced by ensuring that it conforms to the appropriate standard. Researchers would therefore benefit from becoming more acquainted with standardization. Within European enterprises themselves, dialogue and cooperation between researchers and experts active in standardization should be bolstered, while standardization should be made a part of the medium/long term strategy of these companies.

The European Committee for Standardization Technical Board-Action Group on Standardization and Research links (CEN BT/AG STAR) was created in September 1992 to prepare guidelines to develop a more efficient link between European Co-operative R&D and European Standardization, with the aim of improving the speed, quality and completeness of the standardization programme, and promoting guidelines e.g. by participating in the early discussion of European research programmes. **The function of STAR is to identify and prioritize the research needs of standardization.**

CEN Technical Committees are constantly asked to identify needs for research projects that will assist the standards making process or overcome problems that are preventing completion of their work. Prioritization schemes and guidelines have been developed for this purpose. Contributions are also gathered by national delegations from major European industrial research and institutional bodies and

the fora covering given sectors (Sector Fora) within CEN produce strategic papers indicating their research needs and priorities. Therefore, CEN/STAR addresses both 'co-normative research', which interacts directly with ongoing and/or planned standardization activities and 'pre-normative research' which relates to projects likely to generate new elements for standardization. It currently has the status of a Strategic Action and Advisory Group, an active interface between the CEN Technical Committees & Sectors Fora and the European Commission.

The lists of priority projects for 'co-normative' research are submitted for funding from EU Framework Programme sources (the Dedicated Call Approach is described elsewhere in this issue). For 'pre-normative' research, the situation is somewhat different as some industrial sectors are not fully conscious that innovation and pre-normative research have an important part to play in facilitating the fruition of the European internal market and strengthening the competitiveness of European industry. Moreover because the organization of pre-normative research is relatively sector dependent, a uniform approach to identifying specific needs for all domains and sectors can not be employed.

Nevertheless, industry, Government, and private laboratories undertake research of this kind, taking into account the needs of their customers and partners, their prospective activities, the results of market studies, national and international policies, and regulation programmes. The dissemination of results is often very focused but narrow, and there is still little co-ordination or awareness on a broader basis. A key issue is how results are converted into standards. This still occurs at present mostly on a purely *ad-hoc* basis, and there is need for groups undertaking pre-normative research to interact positively and at an early stage with the standardization process (i.e. the CEN project 'EXPRESS Workshops').

In a recent document entitled "Research and Standardization" (EUR 18194), the European Commission emphasized the need for greater consideration of the pre-normative dimension in Community research programmes, in order to foster sustainable growth, competitiveness and interoperability of both products and services emerging from research. It is recognized in particular that standardization is an effective key to achieving the wide dissemination and exploitation of research results. Directorate General XII for Science, Research and Development, is the principal EU channel for co-funding co-normative and pre-normative research. In addition representatives of other Directorates-General have regularly supported the actions of STAR, as have leading members of the European Parliament from the Committee on Research, Technological Development and Energy (CRDTE).

The contribution of the JRC on pre-normative research has been prominent; undertaken principally within the framework of networks (like the European Pressure Equipment Research Council EPERC, whose secretariat is held by the Institute of Advanced Materials). In order to formalize this contribution, in October 98 CEN signed a Co-operation Agreement with the JRC. This will increase the scope for fulfilling the CEN Technical Committees' research needs, as well as lead to new R&D related standardization activities. Other European organizations (i.e. EUREKA, EUROLAB and NORDTEST) are also supporting the aims and objectives of CEN/STAR.

Trend opportunities and challenges for the future

Clearly, the **exploitation** of the results of European research will be boosted by a synergy

between that research and European standardization. Therefore, promotion of Pre-normative Research and Trend Analysis of future needs for standardization is crucial. The activities of CEN/STAR will be strengthened in that direction, in particular through the "Trend Analysis Workshops" organized by CEN, in many cases in collaboration with the JRC. The objective of these Workshops is to provide an overview of the trends and needs for research and future standardization in selected areas, in light of recent research results, industry applications and standardization.

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In Support of Standardization: The New Dedicated Call Approach

C. Saraiva Martins, *DG-XII/CII/3-Measurement, testing, infrastructure*

Issue: In terms of standardization, the 'right standard' exists only if it is available to the market at the right moment and if industry and/or society actually uses it. Frequently, research is needed to ensure a sound scientific/technical basis.

Relevance: One of the major innovations of the Fifth Framework programme (research in support of standardization included) is a clear orientation towards 'user' needs, and a strategically driven selection of topics. Correspondingly, the funding mechanism which focuses on specifically identified research in support of standardization needs for Europe has undergone a certain degree of evolution; it now involves the submission of an 'expression of interest', followed by the publication of a Call for Proposals on selected topics.

In order to interact with the European Commission, the European Standardization Committee, CEN, set up a consultation structure for all its Technical Committees (TCs)

Introduction

Throughout the life of the 4th Framework Programme and under the 'Standards, Measurement and Testing' Programme, the Commission has funded co-normative research projects intended to help solve standardization problems, in conjunction with the standards bodies CEN, CENELEC (CEN Electrotechnical Committee) and ETSI (European Telecommunications Standards Institute). In order to interact with the Commission, CEN set up a consultation structure for its technical committees (CEN/STAR) which has enabled it to make an inventory and draw up a list of priority RTD projects. In CENELEC and ETSI, although using a less formal approach, the topics submitted to DG-XII were nevertheless always ranked according to priorities: 'necessary', 'very helpful' or an 'interesting contribution to standardization'.

The Commission published a new list of specific research topics every 6 months. After 6 calls in support of standardization, 66 out of 130 published topics were financed (52 proposed by CEN, 12 by CENELEC and 2 by ETSI). Experience has shown that this activity has been perceived to be a very positive contribution to the mutual understanding between the Standardization and Research communities in Europe. Many of the results achieved are being incorporated into the European standardization process today.

The New Dedicated Calls Approach

Standardization and Research and Development are interdependent. However, needs do not come only from the European Standardization Bodies, as it was assumed during the 4th Framework Programme. It is known that the quality of standards and time to market can be

substantially improved if the work of the European Standardization Bodies is preceded or complemented with well-targeted pre-normative research actions. The technology necessary for the new standard may be created by a specific research project or may arise as a spin-off from research that was not directly concerned with the development of a standard. The source could come from industry, national and private laboratories and universities. These entities undertake pre-normative research taking into account the needs of their customers, partners, their prospective or future activities, market studies and national or international policies or programmes.

The Commission will continue to fund research supporting standardization. Indeed, the importance of pre-normative research was clearly stated in the Commission's 1997 Communication 'Research and Standardization' (European Commission, 1998). Therefore, and in terms of the 'Competitive and Sustainable Growth' programme, it was decided:

- to open the dedicated calls to include co- and pre-normative research;
- to give the different European Interest Groups, as well as the traditional European Standardization Bodies, the opportunity to participate in the identification of needs.

European industrial associations, European consumer associations, prominent pre-normative organizations, the JRC, etc. can now submit their expressions of interest.

Within the 'Competitive and Sustainable Growth' programme, the generic activity 'Measurement and Testing (M&T)' has been structured horizontally to assist the other specific key actions by providing a coordinating function for Dedicated Calls for co- and pre-normative research. The establishment of a network of contacts with the relevant key actions paves the way for the preparation of a list of publishable topics and also aims to facilitate efficient conversion of relevant research into standards.

In order to ensure efficient and transparent management the funding procedure implemented involves a bottom-up 'Call for Expression of Interest', followed by a top-down 'Dedicated Call':

1. ***Call for Expression of interest*** – this scheme will allow different European groups to identify their needs and priorities. They will prepare a supporting document, which must meet two requirements, and submit it to the M&T Programme. The first requirement is to make the case for the topic to be selected for inclusion in the dedicated call, on the basis of priority of the need. The second is to supply the text in a form such that its style and content will be suitable for distribution if it is selected, i.e. it has to define the objectives and work content to those wishing to present project proposals. Each European group can submit several topics (with the corresponding supporting documents). In the event that the same European Interest Group has more than one topic, then a prioritized list has to be sent.

2. ***A Dedicated Call for proposals*** - is finally published in the Official Journal, restricted to the selected topics which emerged from the socio-economic evaluation of the expressions of needs carried out by external experts and of the intra- and inter-service consultation. For each of the topics which are published, additional information in the form of a supporting document, is supplied on request. Proposals on other topics will not be accepted under these calls.

In its present form, the Dedicated Calls mechanism with its two step evaluation process, provides a flexible and efficient approach:

- in targeting resources towards the most important needs for the pursuit of the Community's objectives and;

The quality of standards and time to market can be substantially improved if the work of the standardization bodies is preceded by well-targeted prenormative

As part of the Commission's support to standardization dedicated calls have been opened to include co- and pre-normative research, and the participation of various European interest groups and standardization bodies has been encouraged

In order to ensure efficient and transparent management the funding procedure implemented involves a bottom-up 'Call for Expression of Interest', followed by a top-down 'Dedicated Call'

The Dedicated Calls mechanism provides a flexible and efficient approach to targeting resources and focusing the efforts of proposers

- in assisting proposers by ensuring that their efforts are directed towards specified needs.

This approach should help to overcome the over-subscription problem; it also allows the publication of new research topics every 6 months. Finally, it allows the setting of priorities for pre-normative research and technical support to standardization with the collaboration of external experts, the different European Interest groups and the relevant key-actions, with every guarantee of fairness and transparency.

The development of the standards needed by industry or society often faces a bottleneck when the required scientific or technical data is not available. The dedicated call mechanism is an effective tool that enables the 'Competitive and Sustainable Growth' Programme to focus on problems such as those found in the development of standards.

A substantially larger share of the budget of the Measurements and Testing generic activity has been allocated to this purpose in the 5th Framework Programme. For the moment, the dedicated call mechanism is only used by the 'Competitive and Sustainable Growth' programme, not just for the research in support of European standardization but also in support of the fight against fraud, the development of reference materials and to support research infrastructures[1].

It may later on be extended to other programmes, should the different Programme Committees consider it worthwhile trying this tool, which M&T has found to be effective in the cases where it has been used.

About the author

C. Saraiva Martins has a degree in mechanical engineering and holds a Master of Science degree in Polymer Science and his doctoral degree is in Material Science, Ceramics. He worked in industry and National Research Institutes in Portugal and the Joint Research Centre in Petten, the Netherlands. Before joining the European Commission, he worked as Assistant Professor at Instituto Superior Técnico in Lisbon, Portugal. In his role of scientific officer of the Standards, Measurement and Testing Programme he has been the contact point at DG-XII for the Dedicated Calls in support of the European policies including research in support of standardization.

Keywords

dedicated call, expression of interest, pre-normative research, standardization

Note

1- Pre- and co-normative research in the areas of agriculture, food, health care, energy and the environment, will be the responsibility of the relevant thematic programmes.

Reference

- Research and standardization - Greater consideration of the pre-normative dimension in Community research programmes, European Commission, Directorate-General Science, Research and Development, EUR 18194, 1998.

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New Trends in Measurement Standards and their impact on R&D

Dr. Andrew Wallard, *National Physical Laboratory*

Issue: Measurement standards and their effects have been regarded as a largely invisible infrastructure of testing and measurement which worked well and which did not attract much attention from economists or policy makers. Recent industrial interest in measurement is moving from the back room to the board room as companies increasingly recognize its relevance to competitiveness and technical barriers to trade.

Relevance: Responding to rising industrial needs the metrology community has formed a voluntary collaboration network named EUROMET which is helping share expertise and develop full confidence in the measurement capabilities of its members. The extent and potential impact of metrological issues on trade such as between the EU and the US is a concern to be addressed through stronger co-operation.

Background

In the techno-economic literature, considerable attention has been paid to the impact of norms on companies, competitiveness and the linked policy issues while very little has been focussed on measurement standards. All this has changed in the last few years for a variety of reasons: recognition that measurement can itself be a stimulus to innovation and that good measurement practice can promote competitiveness and reduce technical barriers to trade; changes in management arrangements for National Metrology (measurement) Institutes (NMIs) as Governments adopted new policies and various privatization models; and - especially in Europe - that the measurement standards infrastructure was a success in policy as well as technical terms.

Measurement and measurement standards are at the heart of the manufacturing process - for product quality, for ensuring the inter-operability and exchangeability of components, for demonstrating conformity with specifications, for consumer protection as well as for ensuring and building confidence in the consistency and equivalence of measurements made in different organizations in different countries. An essential element in national and international measurement is the concept of traceability - the fact that 'traceable' measurements must be made against a reference or standard which is itself calibrated against a standard of superior performance or stability. Ultimately this 'traceability' chain leads to national reference standards and, from there to an internationally agreed system of units and reference standards.

In the last few years it has been recognized that measurement can itself be a stimulus to innovation and that good measurement practice can promote competitiveness and reduce technical barriers to trade

An essential element in national and international measurement is the concept of traceability - the fact that 'traceable' measurements must be made against a reference or standard which is itself calibrated against a standard of superior performance or stability

All national governments assume a financial responsibility for the funding of the research, development and maintenance of standards in National Metrology Institutes (NMIs) or in laboratories designated as holders of national standards

NMIs are not the only bodies concerned with the formal national systems of traceable measurement, and in most countries the NMIs usually only provide calibrations against the country's most accurate standards. The more routine calibrations are made against less accurate standards held in laboratories - often in the private sector - with a formally accredited technical capability and most EU countries operate accreditation systems authorized by national governments. The standards held in accredited laboratories are, of course, traceably calibrated against national standards. In Europe, and in much of the industrially developed world, the International Organization for Standardization (ISO) Guide 25 is used as the relevant accreditation standard - EN 45001 being the equivalent 'Euronorm'.

National Policies

All national governments assume a financial responsibility for the funding of the research, development and maintenance of standards in NMIs or in laboratories designated as holders of national standards. This is because:

- the cost of providing an internationally accepted national standard is too great for any one company, or the market for calibrations is too small for a commercially acceptable return on the investment;
- the calibration services based on national standards must be available to all users, large and small, regular or infrequent, on an equal basis; and
- the international scientific collaboration necessary to validate and compare national standards on a regular basis is usually between commercially independent bodies. The culture of openly sharing 'know how' between NMIs would be jeopardized if it was thought NMIs or nationally appointed laboratories would derive commercial advantage.

The European Response - EUROMET

The current European approach to measurement standards is based on an informal network started in the 1970s, and which has developed into a more formal, but nevertheless voluntary collaboration in EUROMET. EUROMET members include NMIs from all EU Member States, EFTA, the first wave accession countries which comply with EUROMET's membership criteria, Turkey and the European Commission. It is the model on which other 'Regional Metrology Organizations' throughout the world have based themselves. Rather than each European country investing in its own unique national system EUROMET now brings all the key metrology laboratories together for:

- collaboration on research, sometimes carried out under EU-supported projects within the Framework Research Programmes;
- training of the less metrologically experienced countries at well established NMIs;
- the sharing of the costs of expensive facilities; and
- a mutual dependence in order to optimize resources. In this, rather than provide a certain measurement standard or quantity themselves, one member agrees to rely on another for its provision and so establishes a traceability agreement.
- interlaboratory comparisons of standards so as to raise confidence in Europe's measurement infrastructure.

There are now about 30 'traceability agreements' with many more at an informal level. EUROMET also produces guidance notes or statements of best metrology practice and policy which frequently drive similar policies and processes in other parts of the world. EUROMET's strategy is to move further and faster in the direction of mutual dependence and in opening up specialist facilities for use by all.

As well as this high level collaboration, EUROMET's success is also based on intense and highly valued collaborative projects between individual scientists. Far from being the preserve of the handful of the large European NMIs, this collaboration is particularly intensive amongst the smaller NMIs and over 200 individual projects have formally been registered in EUROMET's 10 specialist or technical groups. They range from intimate research collaborations to co-operation on the establishment, or development, of new capabilities. In this way, EUROMET is helping to share expertise and to develop full confidence in the measurement capabilities of its members and, through them, to the commercial and scientific users in member states. Interesting areas of future research collaboration include new ways of offering the NMIs high level capabilities direct to the user, over the Internet, for example, or for challenging new measurement needs in chemistry, food, the environment or measurements of semi-subjective quantities like colour and gloss as well as real-time measurements in the process industries.

Support to the Trans-Atlantic business dialogues

Confidence in accurate measurement is essential to the operation of Community and world trade and to the tests which are needed to underpin Directives or international specification standards. In the past, national differences in measurement practice or, in some cases, requirements that measurements and tests mirror must either be carried out in, or be traceable to, a particular national metrology institute, have been major barriers to trade and has added significantly to export costs. These problems have recently become recognized in the EU-US trade negotiations and there is a proposal that 'calibrations' added to the list of topics to be covered in the TEP (Transatlantic Economic Partnership) negotiations. Anticipating that such apparently erudite technical issues may become significant in the day-to-day trade, the European Commission turned to EUROMET for help and advice. As a result, NMIs from EUROMET collaborated with their US counterpart, the National Institute of Standards and Technology (NIST) in a project designed to enhance international collaboration and establish the extent and potential impact of metrological issues on the trade discussions. The main conclusions were that:

- the European metrology system was working effectively with a high level of mutual acceptance of certificates of tests and traceable calibrations amongst Member States;
- the US legislation frequently required 'traceability to NIST' and was seen by EU exporters as inhibiting trade. In practice, however, technical considerations themselves rarely were significant, but the perception of regulators frequently was that measurements traceable to the EU's NMIs were not accepted in the US;
- US exporters saw the EU's requirement for 'e' marking (to denote compliance with Directives) in a laboratory designated by a Member State Government and, until now, only located in Europe, as a technical trade barrier; and
- the lack of a system of accredited test and measurement laboratories in the US was a source of concern to EU regulators, especially when that was coupled with a low level of familiarity with world quality standards and systems such as ISO 9001 and ISO Guide 25 (for test and measurement systems).

The project has been particularly useful in revealing specific issues of concern which are currently being addressed by the NMIs as well as Regulatory/Authorities, Governments and the EC.

The current European approach to measurement standards is based on an informal network started in the 1970s, and which has developed into a more formal, but nevertheless voluntary collaboration in EUROMET

The fact that differences in national practice can hinder trade has recently become recognized in the EU-US trade negotiations and there is a proposal that 'calibrations' be added to the list of topics to be covered in the TEP (Transatlantic Economic Partnership) negotiations

The International Bureau of Weights and Measures (BIPM) is working to create a Mutual Recognition Agreement (MRA) by NMIs within which they will recognize each other's measurement capabilities and calibration or measurement certificates

The World Scene

In a much broader, world-wide initiative, the members of the 'Metre Convention' - 48 of the world's major economies - are working together to create a **formal** system of mutual acceptance of test and calibration certificates. This initiative, launched by the International Bureau of Weights and Measures (BIPM) will lead to a Mutual Recognition Agreement (MRA) by NMIs within which they will recognize each other's measurement capabilities and calibration or measurement certificates. This MRA will be based on an intensive and comprehensive network of comparisons of measurement standards first at the world, then at the regional (EUROMET) level and a formal quality system for the production of calibration certificates. The comparisons, when combined with validated statements of NMIs calibration capability (accuracy, range of measurements) will enable BIPM to create a widely accessible data base which will enable enquirers to ascertain any differences between national capabilities in any area of interest. It will also enable Regulators or Government Bodies concerned with trade to determine whether they need to be concerned about any metrological differences between countries and whether these are significant as far as compliance with trade regulations or specifications is concerned. The global MRA will be signed in October 1999 and will involve the majority of EU Member States as well as many of those on Accession paths.

New priorities: new structures

NMIs serve industry and are funded by the public sector to do so. In recognition of this ever-closer relationship, many are developing new networks, launching industry-based user clubs and finding new ways of setting research priorities based on the techno-economic impact of their work. Impact studies show returns of several hundred percent. In many cases, the NMIs are responding to their market-led status and are adopting new models so as to introduce best private sector practice in its research management. In the NPL's case, for example, the laboratory is owned by the UK Government but is operated by a private sector contractor. Savings of some 20% have resulted and the laboratory is expanding rapidly to meet new research needs.

Conclusions

Far from being an esoteric "next decimal place", subject metrology in Europe, and EUROMET is widely regarded as a success, is emulated by others and is regularly consulted on technical issues by the Commission and by Governments.

The international system is indeed working and co-operating in new ways. First, regionally based organizations like EUROMET collaborate more intensively to share the cost and reduce the risks of research and so as to offer greater value added and a more efficient infrastructure to European industry. Secondly, metrology is rightly recognized, much more than in the past, as a potential technical barrier to trade, as an important element in competitiveness, consumer, health and environmental protection. Thirdly, the NMIs are building on their technology base and are reacting to the needs of a more 'measurement aware' user community in industry, through expanded technology transfer, advisory services and direct interaction with firms.

Measurement concerns have a direct bearing on European industry which national and community policies cannot disregard. When working at a Community level on legislation to improve the workings of the single market, encouraging effective infrastructures in Accession States, or negotiating the technical aspects of trade or international cooperation agreements,

measurement issues are one of the practical aspects which need to be considered so as to implement the policy as effectively as possible. They therefore need to be considered at an early stage in the policy formulation process and in inter-service discussions. The strength of the European position is that we have the basis of what could be the most effective system in the industrial world. It needs to be strengthened still further and extended to the less well developed regions as well as be a key part of the infrastructures in Accession countries as they move from a culture of central regulation to one which recognizes free market principles.

Measurement consideration also influence other Community policy makers in other areas-such as research strategies for particular sectors or long term environmental considerations which can only be truly monitored if the measurements are based on truly accurate and unchanging reference standards. EUROMET and the European NMIs are ready to support these policies and concerns and would be pleased to be consulted and comment on the relevant specialist aspects.

It is important to strengthen and pursue the process of further integration and mutual dependence with the aims of efficiency and effective use of national as well as European funding mechanisms in mind. The objectives are clear: we look forward to meeting them and tackling European needs for the next century.

Keywords

measurement standards, industrial competitiveness, international collaboration

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Promoting Equal Accessibility of Genetic Testing Services of High Quality in the EU Through the Development of European Standards

Ulf Kristoffersson, *University Hospital Lund* & Karin-Elisabeth Rosén, *SAUL*, and Per Sørup, *IPTS*

Issue: The rapid pace of gene discovery, and the associated potential within molecular medicine, raise the challenge of identifying information about a plethora of mutations in disease-related genes in an as-yet healthy population, through predictive and pre-symptomatic genetic testing. Genetic testing services used in clinical diagnosis of genetic disease, however, are neither regulated nor standardized at an EU-level. Moreover, recent surveys, indicate that a large number of diagnostic laboratories do not have access to or do not participate in external quality programmes and therefore make unacceptable levels of genotyping errors. The development of European standards for genetic testing services in Europe could thus be an important step forward in the framing of quality assurance processes.

Relevance: Identifying at-risk populations and offering effective preventive treatment strategies will be of substantial benefit for public health in the future. Because of the potential for large numbers of rare genetic diseases (so-called orphan diseases), genetic testing will in many cases have to be provided by specialized reference laboratories at a European level. In order to promote the free circulation of genetic testing services within the EU internal market, a harmonization of regulations and/or standards to ensure equal access to genetic testing services of high quality is highly desirable.

New research, such as the human genome project, is opening up the technical possibility of a wider range of genetic tests being made available for diagnostic and predictive purposes

Introduction

Genetic testing is currently undertaken in cytogenetic, biochemical and molecular laboratories, and the effective diagnosis of genetic disease is dependent on a wide range of both clinical and laboratory experience. Along with the rapid development of the Human Genome Project (the HUGO-project is designed to map and sequence the complete human genome by the year 2005), the number of laboratories that offer genetic testing services is increasing in Europe. Despite valuable quality assessment initiatives from the genetic specialists' professional organizations, genetic testing services in Europe are delivered under very different conditions (Harris R, Reid M. 1997) and regulatory frameworks. As a genetic test can be used for both diagnostic and predictive purposes, the information obtained differs in many ways from

other tests performed in health-care. Any consideration of the potential far-reaching medical, legal, psycho-social, and ethical consequences of a false positive (not-normal) genetic test result, immediately raises legitimate concerns as to how to ensure the quality, safety and efficacy of genetic testing services in Europe. This, in turn lies at the centre of the proposal to develop European standards.

Genetic Disorders

Most genetic disorders are considered to be polygenic, or multifactorial (e.g., most cancers, hypertension or coronary heart disease). These diseases are very complex as they involve an interaction between a genetic predisposition (susceptibility genes), and environmental and life-style factors. A positive (not-normal) genetic test result may thus be a poor indicator of the likelihood of actual onset of disease. The identification of a monogenic or a single-gene disorder, (e.g. hereditary breast cancer cystic fibrosis), on the other hand, may predict the onset of disease with far greater certainty. However, because of the variability of gene expression, the severity of symptoms is even harder to predict in each individual case. Thus the necessity of a professional interpretation of test results, together with the desirability of access to appropriate genetic counselling.

A clear challenge to the health-care sector is the current dearth of genetically trained staff. Emerging genetic testing requires specific abilities to assess the risks and benefits of genetic testing for different genetic diseases. But it is widely acknowledged that the level of genetic literacy and experience with the emerging genetics techniques among general health-care professionals is rather limited (Stephenson, 1997). This is, of course, due to the novelty of these developments. A recent study, for example, reported that physicians misinterpreted some 30% of the cases of genetic test results for familial colon cancer (Giardiello FM, Brensinger JD, Petersen GM, *et al.* 1997). Genetic tests for most genetic diseases do not yield what could be considered clear-cut implications, and their medical management is therefore often uncertain. As science and technology develop, new and more effective drugs and treatments will be made available. Better and more precise medical predictions will then be possible, and society will have a better knowledge and experience in handling genetic information. Hence the estimated increase in the use of genetic testing services in the future.

The Free Circulation of Genetic Testing Services

Since a large number of genetic diseases are what can be considered rare diseases (orphan diseases) with a very low frequency among population groups, it is unrealistic to imagine that laboratories in each EU member state alone could meet the future genetic testing demand for many genetic diseases. The public availability of genetic testing for these diseases will more likely be depend on using cross-European genetic testing services provided by specialized reference laboratories in other EU member states. Thus the necessity of ensuring the free circulation of genetic testing services in Europe. Any attempt to regulate or standardize genetic testing at only a national level - something that will certainly emerge unless actions are taken at a European level - could thus become an obstacle to the internal market and threaten the equal accessibility for genetic testing services.

European Regulations

Currently genetic testing services are not regulated or standardized at EU-level. A major reason for this seems to have been that genetic

The complex interactions and varying role of genetic factors mean these tests often do not give simple 'yes/no' answers but require skilled professional interpretation

At present the required skills are not widespread among general health-care professionals and consequently tests may frequently be misinterpreted

The large number of rare diseases which may eventually become the subject of testing means it is unrealistic to imagine that each EU Member State will be able to meet demand alone

A Europe-wide genetic testing industry will require harmonization and standards. However, the emphasis of the current regulatory framework is on health-care related products rather than technical services of this kind

Recent European quality assessment studies indicate that among 136 diagnostic laboratories no less than 35% have a level of genotyping errors that would be considered unacceptable in routine testing

Quality throughout the testing chain as a whole depends upon correct identification of individuals, interpretation of results, counselling, etc. only the technical testing part of which is appropriate for standardization at European level

testing is often considered directly related to health-care services. But the testing procedure itself should probably be more accurately considered to be a technical service, even if the information so generated has implications for public health. Genetic testing services do not fall under the Council Regulation 2309/93/EEC, concerning the centralized procedure for medicinal products for human use, nor do they fall under Directive 98/79/EC for *in vitro* medical devices, which concerns only *products* to be placed on the market. Genetic testing is currently undertaken in both professional and research laboratories, and commercial testing has already been launched for a number of different genetic disorders (e.g., Alzheimer's Disease, breast cancer). Consumers, as a result, can, to an increasing extent, be approached directly by private companies offering their genetic testing services without proper genetic counselling. There is a risk that the context of genetic testing services is no longer confined to the interaction between patient and physician in a health-care setting. As pre- and post- test counselling is regarded as a part of genetic testing this places pressure on any company offering tests direct to consumers to develop routines to inform the customer correctly about the use of the offered product. Taking into consideration that we are dealing with predictive genetic testing, in as yet healthy individuals that may have a predisposition to develop a specific disease, the issues of validation and quality assurance of the technical testing procedure become more akin to issues of consumer protection. (Harper 1997)

Genetic testing services offered in the EU-member states operate under very different conditions. In certain member states, only designated laboratories are allowed to undertake genetic testing (Belgium). In other member states, genetic testing laboratories are subject to reimbursement agreements with insurance companies and medical professional associations, something which often includes certain quality assurance schemes (Germany, France). In other countries, as a consequence of the lack of both national (Sweden, Spain) and EU-regulations, genetic testing may still be performed in research laboratories which only have a temporary interest in offering the service. These laboratories are not reimbursed for their services, although their test results may still be used in clinical diagnosis of potentially lethal but incurable genetic diseases, despite the lack of technical and administrative skills to provide a quality assured service.

European Quality Assessment Initiatives

Recent European quality assessment studies indicate that among 136 diagnostic laboratories no less than 35% have a level of genotyping errors that would be considered unacceptable in routine testing (Dequeker E., Cassiman J-J., 1998). This problem has been acknowledged and different quality assessment initiatives have been developed within the European professional bodies of genetic specialists such as EUCROMIC and EuroGAPP. The former has organized a workshop on quality assessment and published suggestions for European guidelines for prenatal diagnosis (Kristoffersson, U., 1997). The latter, which is constituted by members of the European Society of Human Genetics' Performance and Public Policy Committee intends to hold discussions over the next two years concerning the necessity of developing European guidelines for genetic services. An important aspect, which may be subject to misconceptions about ongoing discussions, is that the technical part of the genetic testing procedure forms part of a much more complex testing chain. The quality throughout the whole testing chain is, of course, dependent on the successful identification of at-risk individuals to be tested, the correct clinical interpretation of test results (predictive values), as

well as individual and family counselling activities to develop preventive screening programmes, medical treatments and psychological support. However, while the administrative and technical parts of genetic testing could be successfully standardized at European level, the practical organisation of genetic counselling activities at population levels and medical management will continue to depend on the health-care programmes provided for in the different member states in accordance with the principle of subsidiarity.

The European Standardization Process

Standardization and harmonization processes provide essential tools in the political, socio-economic and technical integration of contemporary Europe. The so called New Approach was developed in the process of bringing about the internal market and European economic integration through the free movements of goods, workers and services. This procedure distinguishes the standard drafting process from the drafting of technical regulations which is undertaken by a national authority. It should also be pointed out that standards allow greater flexibility than regulations as they are regularly revised so as to be kept abreast of technological developments. This is of importance in areas characterized by rapid developments. Therefore a relevant question to pose is whether the development of European standards could alleviate or lower the number of errors currently made in the genetic testing procedures. **While misinterpretations of data reflect on the qualifications of the staff, the administrative and technical errors made could well indicate the lack of standardized and validated testing procedures.**

Conclusion

In considering the accelerated pace of gene discovery and the increasing number of laboratories of yet uncertain quality offering genetic testing services, and also the possibly far-reaching ethical, legal, medical and social consequences of genetic test results, the development of European standards for genetic testing services could well provide a useful tool to promote equal accessibility to genetic testing services of high quality in the EU. It also appears to be the case that the European standardization process could promote desirable terms of harmonization at an EU level, in rapidly developing areas as, for example, life sciences. Further prospective analysis will be required to assess which fields and applications would benefit from standardizing measures. This should however include a pro-active engagement in the search of realistic alternatives to avoid adverse consequences, especially in relation to the complex interactions which tend to breach traditional disciplinary boundaries.

Standards allow greater flexibility than regulations as they are regularly revised so as to be kept abreast of technological developments. This is of importance in areas characterized by rapid developments

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Keywords

genetic testing, quality assurance, European standards

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Innovation and Standardization

Torsten Bahke, *Director of DIN*

Issue: Standardization is internationally accepted as an essential, well-documented means of reaching agreements, and is frequently used as a tool for the rationalization of production and trade. However, a number of innovative sectors have now emerged for which traditional standardization is unsuitable, and in order to meet the new challenges, DIN has developed a faster way of producing normative results: Research and development phase standardization.

Relevance: This new approach to standardization has grown out of a need for structural change within standards bodies, industrial research organizations and regulatory institutions. Such changes would enable standardizers, researchers and regulators to respond more effectively to rapidly developing technologies. Since these developments are global in nature, R&D phase standardization must also take place at a global level.

Introduction

The traditional standardization process commences after the development phase. It reflects the current state of technology, and is an expression of a consensus reached by all interested parties. It is particularly relevant for questions of rationalization in Tayloristic production (e.g. introducing standard methods of measurement and reducing the number of product types).

Over the last few decades, however, the scope of German Standards has broadened rapidly as a result of the increasing influence in all industrial sectors of aspects such as safety technology, environmental protection, ergonomics and consumer protection. In response, standardization has now departed from its original concern with largely technical matters, and is even becoming an integral part of the economy. In addition, efforts to promote harmonized requirements for the Single European Market in the form of European Standards (EN) have led to an increase in standardization activity at the European level.

This new process is one of mutual benefit in which changing needs can be constantly taken into consideration, and is one to which ongoing research and development work can respond. An internal study by the DIN Standards Committee for Information Technology (NI) summarizes the modern role of standardization as follows:

"Standardization must be an integral part of a development process for products, independent of the manufacturer. Within this process, standardization can define goals and encourage developments beyond the standards bodies themselves, and can also respond to new developments which establish themselves in the

Over the last few decades, the scope of German Standards has broadened rapidly as a result of the increasing influence in all industrial sectors of aspects such as safety technology, environmental protection, ergonomics and consumer protection

There is a need for standardization to accompany the entire R&D phase to enable future-oriented solutions to be introduced at the earliest possible stage

Increasingly manufacturers position their products through quality rather than price. To remain competitive they need to be able to innovate rapidly, supply systems globally, meet safety and environmental criteria and encourage networking of human resources

Developments in these directions discussed here will require a consensus on the characteristics of the systems used, testing and measuring procedures, descriptions of characteristics and definitions of interfaces

marketplace, creating the necessary structure to absorb them into the standardization process for wider use."

Research and Development Phase Standardization

During the last two decades, the development and application of new technological processes have increasingly moved away from individual technologies to system technologies, which are closely linked to scientific research. Technological systems and their components must be developed on the basis of current research in order to fulfil practical requirements such as the effective use of materials, high resistance to wear and low environmental risk. Individual technology sectors such as biotechnology, building technology, electronics, and communications technology can only be effective on the market if they incorporate aspects of health and safety, environmental protection, and consumer protection. As modern systems technology has become an increasingly important factor in technological change, and as information and communications technology has entered all areas of society, technical developments have emerged for which the traditional instruments of standardization are insufficient. There is a need for standardization to accompany the entire R&D phase to enable future-oriented solutions to be introduced at the earliest possible stage. The German approach to this issue is R&D phase standardization, which can be applied to innovative sectors as a complementary instrument to traditional standardization.

Changes in technology have been accompanied by changes in the marketplace. Nowadays, manufacturers position their products less through pricing than through quality. This means that their products must not only function, but also be environmentally safe, delivery must be punctual, and replacement parts and service must be available in the long-term. Today, the most important competitive factors for companies seeking to secure their existence include:

- The ability to make rapid changes to products to meet customers' requirements (rapid innovation)
- The ability to supply systems globally, both as complete units and as separate components
- The ability to develop systematic concepts to satisfy environmental aspects, safety requirements and health protection legislation
- The ability to mobilize the organizational potential of personnel by creating, for example, an environment for human networking

Rapid innovative developments, characterized by short product lives, cannot be fully served by traditional standardization procedures. Network-based technological systems need standard interfaces and specific data formats in order to function, even at the development stage. International cooperation on buying in components is not feasible without agreement, i.e. without international standards. Self-organization as a group in the work environment, nowadays referred to as the "fractal factory", is inconceivable without clear information and a shared understanding of the system being used.

None of the technical developments mentioned here will be possible in the future without a consensus on the characteristics of the systems used, testing and measuring procedures, descriptions of characteristics and definitions of interfaces. This will not be possible without harmonization, the essence of standardization. Traditional standardization cannot achieve this. The close interaction between research, development and standardization provided by R&D phase standardization, however, makes it possible for all interested parties to identify

weaknesses at an early stage, and to examine solutions offered by scientific research and industrial technology.

The activities of the Production Commission Office of DIN illustrate an effective interaction between standardizers and researchers at the development stage. These R&D phase standardization activities include:

- Analysis of objectives and consultation on standardization relevance
- Expert analysis in the field being standardized
- Assisting the project partners in determining standardization potential
- Drafting proposals for R&D phase activities and recording standardization results in the appropriate normative documents (Technical Reports, Publicly Available Specifications (PAS), prestandards, commentaries, etc.)
- Consultation on project activities that may be relevant to R&D phase standardization
- Consultation and providing contact with the appropriate standardizing bodies, e.g. DIN Technical Committees
- Providing support during standardization procedures, i.e. by processing and making proposals in the relevant Technical Committees, and providing the necessary documents
- Assistance with draft proposals and proposed texts for standards in accordance with the relevant national, European or ISO regulations
- Documentation and presentation of R&D phase standardization activities.

New Standardization Instruments

Standards are acknowledged technical rules that are drawn up on a consensus basis by experts representing all interested parties. In many cases, however, informal documents such as company standards suffice, and full consensus is often not necessary. DIN has found an effective way to fill the gap between consensus-based standardization and informal standards: With the **Publicly Available Specification (PAS),** DIN makes use of a compromise between full consensus and quick results, a strategy that is also used at the European and international levels. Consensus-based

To fill the gap between consensus-based standardization and informal standards DIN uses Publicly Available Specifications (PAS) as a compromise between full consensus and quick results, a strategy that is also used at the European and international levels

Table 1. Research and Development Phase Standardization Activities for selected sectors at DIN

Production technology	Since Spring of 1997 DIN has been involved in "Production 2000", an extensive research programme coordinated by the BMBF (German Federal Ministry for Education, Science, Research and Technology).
Laser technology	With its development programme "Laser 2000", the BMBF provides support for over 300 projects involving standardization coordinators from DIN. Many new laser-assisted measurement and testing methods have been developed and documented in prestandards; this will considerably increase the precision and quality of products and will improve analytical methods.
Services	At present, European standardizers are concentrating on branches such as tourism, the hotel industry, transportation, accountancy/auditing, trade fair management, and - to a certain extent - public services. Sectors which have received less attention, include professional services, engineering services, project planning, and technical services such as diagnosis, repair and maintenance. Currently, DIN and several other institutes are discussing the possibility of standardized reference models for various branches (e.g. public administration). DIN Technical Report 75 introduces standardization to research into services of the future.

standardization is not affected and will retain its significance. The European "CEN Workshop Agreement" (CWA) is similar to the PAS.

DIN was motivated to simplify the procedure for **Prestandards** (DIN V) in 1984, enabling them to be produced more quickly, concurrently to technical developments. This means that recommendations can be made during the R&D phase, accelerating and supporting the subsequent development of products and systems. Similar steps were taken at a European level, where European prestandards (EN V) were introduced, providing technological sectors with early support from European standardization.

Conclusion

To conclude, we would like to emphasize once more that R&D phase standardization will not replace traditional standardization; rather, it will be a crucial complementary element wherever complex systems and rapid innovation are involved. It is the common goal of the standards bodies of all EU and EFTA nations to harmonize national standards. In light of this Europe-wide harmonization, we consider it crucial for standardization to play an increasingly important role in European research. The German model for "R&D phase standardization" presented here can serve as an example for a European strategy.

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Torsten Bahke holds a doctorate in Engineering. After working as Assistant Managing Director, Krupp South Africa, Head of Projects for Bulk Material Systems, Krupp Industrietechnik GmbH, Duisburg, Head of Executive Board of Directors, PHW Anlagen und Systeme GmbH, St. Ingbert and Member of the Executive Board of Directors, Krupp Fördertechnik GmbH, Essen, he started working at DIN German Institute for Standardization in 1997 as Director of Strategy and has been the Director of DIN (CEO) since 15.03.1999.

Keywords

standardization, R&D phase standardization, services, laser technology, production technology, Publicly Available Specification (PAS)

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Analytical Methods and Reference Materials in Standardization

Jean Pauwels and Adela Rosa Rodriguez, *IRMM-JRC*

Issue: All trade in the single market depends on the mutual recognition of measurements that determine the vital properties of traded goods (e.g. genetically modified organisms in corn or hormones in imported meats). Reference materials and reference analytical methods are the cornerstone of this 'common language' for trade and thereby serve to ensure the quality, safety and reliability of a vast range of traded goods and products.

Relevance: The production, certification and validation of reference materials and methods enables the development of new standards and the proper implementation of existing ones. In this way European Directives related to industrial competitiveness, health, consumer, worker and environmental protection can be implemented and European policies can be monitored.

Introduction

Dispute-free international trade, the mutual acceptance of goods and the implementation of world-wide health and nutritional policies, all demand reference methods and materials to accurately and precisely assess the quality of traded goods. They help prevent barriers to trade, support legislation and, in the end, contribute to promoting the competitiveness of European industry. They must have a broad basis of acceptance and be easily and generally applicable, and therefore require intensive international collaboration for their development and validation. Standardization processes are, therefore, highly dependent on continuous input from a variety of research and development sources, such as private and public research institutes, industrial organizations and government departments, as well as from the European Commission (EC) services, including the Joint Research Centre (JRC).

The JRC Institute for Reference Materials and Measurements (IRMM) in Geel, with over 35 years experience, has carefully tailored its facilities and nurtured its expertise specifically for reference materials and reference methods. Such analytical methods and reference materials serve towards the implementation of international standards and Commission policies.

Development of Reference Materials

IRMM's Reference Materials unit currently contributes to the production of reference samples and the certification of new candidate reference materials. It also supplies certified

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Metals are among the most widespread of materials in our society and they are often found in critical applications where quality is vital for safety. Defining the strength, stability and reliability of metals requires test samples with which to calibrate testing equipmen

European standards on PCDD and PCDF emissions have created a need for reference materials so as to be able to verify their implementation

Environmental monitoring authorities and research institutions are, for the first time, about to obtain the required reference material that will enable them to verify the accuracy of their chemical (elemental) analysis of aerosols

reference materials needed for the correct implementation of already existing standards.

Certified reference materials for physical characteristics testing of metals

Every day life increasingly relies on the quality of metal components - be it for the construction of buildings, industrial complexes, roads or the development of modern means of transport such as cars, buses, trains, ships and planes. The quality of such metals is defined in terms of their strength, resistance, stability and reliability.

An important property qualifying the quality of a metal is its impact toughness, which is defined as its ability to resist fracture under the effect of shock loading. Impact toughness is commonly measured using the so-called Charpy V-notch test to determine the energy required to fracture a standard test sample. This test, first described by the American Standards Testing and Measurement (ASTM) organization some 40 years ago, specifies that all measurement instruments have to be verified periodically using reference specimens.

Meanwhile, European laboratories collaborating within the European Committee for Standardization (CEN) with the support of the European Community Bureau (BCR) have developed a European Standard. This standard not only specifies the dimensions and tolerances of both the test pieces and the testing machine (EN 10045-1), but also specifies the conditions for the direct alignment and indirect verification (using reference samples) of the impact testing machines (EN 10045-2). Certified reference materials, in the range 30–160 Joule, are currently being produced and certified by IRMM. Future plans include the launch of BCR CRM 661 in 1999. This reference material is for ambient temperature tensile testing and the verification of testing machines according to European standard CEN 10002.

Certified reference materials for PCDD and PCDF emission control

The EC has set up a Directive to deal with the reduction of various contaminants from hazardous waste incineration plants, including polychlorodibenzo-p-dioxins (PCDD) and polychlorodibenzo furans (PCDF). The Council adopted a common position (EC 26/94) on a maximum emission limit for PCDDs and PCDFs of 0.1 ng I-TE/m^3, to come into force as soon as appropriate standards allow its implementation. Presently, IRMM contributes to the preparation and certification of several CRMs (standard solutions, fly ash) related to PCDD and PCDF monitoring plant emissions operating at the legally admissible 0.1 ng I-TE/m^3 level. In this area it is expected that the 11 reference materials will become available as BCR reference materials in 2000.

Aerosol Reference Materials for Pollution Control

European Directives related to pollution control and health protection are becoming more and more specific in terms of their described properties, be they physical or chemical. Air quality depends not only on the total mass of suspended particulate matter but also on the inhalable size fraction of particulate matter and on the concentration of specific gases.

Environmental monitoring authorities and research institutions are, for the first time, about to obtain the required reference material that will enable them to verify the accuracy of their chemical (elemental) analysis of aerosols

(emission and immission) collected on filter samples. Now that a first generic ambient aerosol material has been collected, the production control and certification of this material is being carried out. The characterization of these reference materials for their heavy metal content will be performed within IRMM using the following methods: Particle Induced X-ray Emission (PIXE), Neutron Activation Analysis (NAA), Inductively Coupled Plasma Mass Spectrometry (ICP-MS) and Atomic Adsorption Spectrometry (AAS).

Certified reference materials for food and water contamination by bacteria

Nowadays food is increasingly imported and exported across borders and water is, by definition, an international medium. Contamination of food and water by bacteria is a regular occurrence and virtually everyone can recall the most recent outbreak of for example E. Coli or salmonella. Therefore, it is imperative that national or regional control laboratories perform and communicate their results in a transparent and comparable way. As bacteria are tiny living micro-organisms which change, reproduce, and die, their accurate counting in food and water is extremely complex and can only be achieved by strictly following described written procedures, which must be controlled and validated using appropriate certified reference materials.

In this context, the development of stabilization procedures for larger micro-organisms in spray-dried milk powder was an important breakthrough, which allowed the production and certification of six BCR CRMs which are distributed by IRMM. Additionally IRMM regularly verifies the validity of these materials and organizes new certification campaigns as required.

Certified reference materials for the detection of genetically modified organisms

The genetic modification of agricultural and food products will undoubtedly gain momentum as the new millennium ushers in new era for science and technology. According to EC Novel Food Regulation (EC 258/97), a novel food or food ingredient shall be deemed to be no longer equivalent if scientific assessment can demonstrate that the characteristics are different when compared to conventional food. To implement this directive there is an underlying scientific obligation to accurately and clearly identify food products that have been produced using genetically modified ingredients. International measurement evaluation studies were organized with the aim of, first, developing and validating screening and quantitation methods for the detection of GMOs in food and, subsequently, laying down official methods in written standards and EC legislation. As a result in 1997 the IRMM started to produce reference materials of certified GMO composition in collaboration with Fluka Chemie A.G. and the JRC's Environment Institute. These reference materials found immediate use in several international collaborative studies aiming at the validation of GMO measurement techniques such as Polymerase Chain Reaction (PCR) and the well known ELISA methods. At present, six different reference materials of Roundup Ready soya (IRMM CRM-410) and Bt-176 maize (IRMM CRM-411) are available and, additionally, the preparation of Bt-11 maize reference materials is being planned.

Certified reference materials for enzyme activity

Pure enzymes from human, animal or recombinant origin are routinely used in clinical diagnosis as markers for various disorders such as

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In the cosmetics products field, IRMM has developed a method which enables the identification and quantification of a broad spectrum of regulated substances in hair dye forming compounds

brain damage and cardiac or hepatic diseases. To support and enhance the accuracy, precision and reliability of these clinical diagnoses, certified reference materials for various enzymes are very much in demand. Several enzyme CRMs were produced in the nineties by BCR in order to help standardize the measurement results of enzyme catalytic concentrations in serum according to procedures laid down by the International Federation of Clinical Chemistry (IFCC). These procedures are intended to ensure the transferability of the IFCC method to various laboratories and also enable comparisons of results between different analytical methods used in such laboratories.

In the latter half of 1996, a collaboration agreement was signed between IRMM and IFCC. New standard operating procedures were discussed and agreed upon within the IFCC Working Group on enzymes, and the IFCC methods are now being revised accordingly. Already in 1999, five existing enzyme CRMs will be re-certified according to these new standard procedures and two more enzyme CRMs will be produced and evaluated for certification.

Development of reference methods

Candidate Reference Method for oxidative Hair Dye Analysis

Member States are responsible for conducting analyses of cosmetic products when such analyses are deemed necessary for the enforcement of the law and/or the control of EC regulations. Inspection authorities as well as the cosmetics trade and industry need reliable analytical methods for the identification, characterization and/or quality control of specific active ingredients or formulations in such cosmetic products.

The IRMM is supporting pre-normative research on behalf of the Cosmetic Directive (76/768/ECC) (93/35/EEC) and its 6th amendment through, amongst other activities, developing a reference method for the analysis of oxidative hair dyes. The concentrations of these substances are either restricted or indeed completely prohibited. To identify and quantify these substances in possible hair dye formulations, IRMM developed a method which enables the identification and quantification of a broad spectrum of possible hair dye forming compounds.

As a follow up, a list of frequently used matrix products and their concentrations as applied to hair dye formulation was provided by COLIPA (Comité de Liaison Européen de l'Industrie de la Parfumerie, des Produits Cosmétiques et de Toilette). In this context an international intercomparison campaign will be organized by IRMM.

Conclusions

The role of IRMM in supporting standardization through the development of analytical methods and the production and distribution of certified reference materials is essential, as it not only allows the development of new standards, but also the correct implementation of existing ones. As shown in the examples described, this activity touches upon essential aspects of modern society, such as industrial competitiveness, environmental monitoring, consumer protection and public health.

In addition, these activities are being performed in close collaboration with international organizations, as well as university, government and industrial laboratories, which have been requested to participate in the preparation and/or characterization of reference materials and methods.

Keywords
analytical methods, reference measurements, reference materials

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Research in Structural Mechanics in Support of Standardization

Artur Pinto, *ISIS- JRC*

Issue: The recent Kobe 1996 (Japan) and the Umbria-Marche 1997 (Italy) earthquakes have highlighted the urgent need for new actions in the field of assessment and strengthening of existing constructions. This is particularly relevant for the design of earthquake resisting structures because, in such cases there are also considerable hazard and risk differences between European countries.

Relevance: Safety and the need to preserve European cultural heritage require that special attention is devoted to the challenging task of maintenance of the existing centuries-old heritage. Yet, setting up uniform European design codes for civil engineering structures (EUROCODES) has run into a number of difficulties due to the different national or regional traditions together with the lack of a complete set of norms covering materials and types of structures.

The Institute for Systems Informatics and Safety (ISIS) is able to use its broad knowledge of public risk to provide neutral and independent advice and support to European Policies and promote collaborative research activities

Introduction

There are several aspects that should be underlined in the research supporting code development. First, the end product itself, i.e. the standard, should provide minimum, or better still, optimum safety levels for citizens and goods. Secondly, uniform standards have a clear economic impact, through their promoting the competitiveness of European industry in internal and external markets. Thirdly, there are two major benefits to carrying out these efforts as part of cooperative research programmes: 1) the increased probability of getting agreement at high decision-making levels, and, 2) promotion of the European scientific/ technical community, which is taking advantage of the experience and outcome of collaborative research projects involving different institutions and researchers with complementary facilities and expertise.

The Institute for Systems Informatics and Safety (ISIS) is able to use its broad knowledge of public risk to provide neutral and independent advice and support to European Policies and promote collaborative research activities. At present, the Structural Mechanics Unit of the ISIS Programme is focused on safety of buildings, means of transport and preservation of European cultural heritage. Indeed, a few research projects in support of Eurocode 8 recently performed, involving ISIS and several European universities and research laboratories, clarified open issues and developed normative proposals, which are currently under discussion for approval in the CEN Technical Committees. With funding from its institutional

and competitive budgets ISIS is preparing a new action on innovative techniques for strengthening existing structures. This work will also contribute to calibration of the relevant part of Eurocode 8.

The research performed at ISIS in the field of earthquake engineering involved experimental and numerical work and is being carried out in cooperative research projects. This research is in effect the area with greatest direct relevance to standardization and codification (CEN-TC250). However, the institute can provide support in other areas in the field of structural mechanics. Examples are the institutional projects on Structural Crash Safety Enhancement of Vehicles and Road Equipment by Precision Impact Tests and the Computational Mechanics Applied to Structural Safety. Furthermore, the ISIS institutional projects on Information Technologies and Medical and Health Telematics were identified as relevant to a number of CEN Technical Committees.

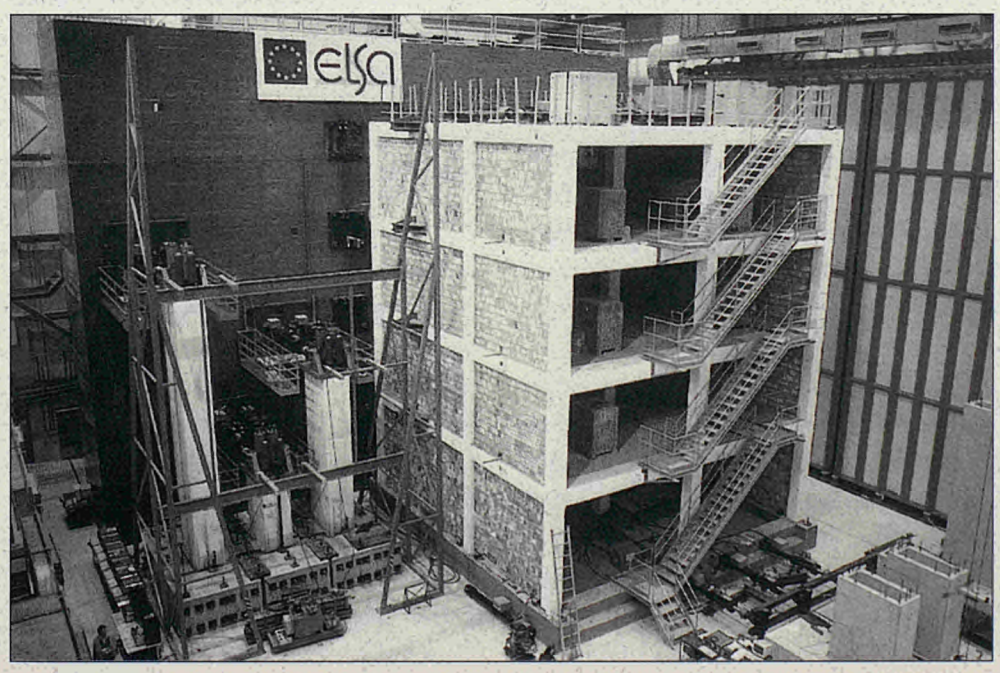
A unique testing facility in a co-operative and coordinated European network and its relevance to industry

Particularly relevant to issues of structural safety is the European Laboratory for Structural Assessment (ELSA), which has one of the world's largest reaction-walls and has implemented a fully digital testing method, the pseudo-dynamic testing method, able to perform seismic tests on full-scale buildings and bridges (see Figure 1).

This unique testing facility and the existing expertise are being applied to develop innovative concepts and standards. Several tests on buildings and bridges have been carried out (ECOEST-PREC8, 1997) under the framework of PREC8, a co-operative research project in support of Eurocode 8.

The ELSA facility is a member of the European consortium of earthquake engineering testing facilities (ECOEST2), which groups together ELSA

Figure 1. Building and bridge models tested at the ELSA laboratory



The Structural Mechanics Unit at ISIS focuses on the safety of buildings and means of transport. It is currently preparing a new action on innovative techniques for strengthening existing structures as part of Eurocode 8

Particularly relevant to issues of structural safety is the European Laboratory for Structural Assessment (ELSA) which is able to perform seismic tests on full-scale buildings and bridges

The Innovative Seismic Design Methods will involve testing techniques suitable for retrofitting to existing buildings on large-scale models

The ELSA laboratory and four European institutions recently concluded a competitive pre-normative research project launched by DG-III on seismic assessment of structures, focusing on composite (steel-concrete) structures and reinforced concrete frame buildings with ceramic-brick infill panels

and several European shaking-table laboratories located in Bristol, Athens, Paris, Bergamo and Lisbon (Severn, 1998).

A large-scale research programme focusing on Innovative Seismic Design Methods and Concepts developed under the framework of the ICONS research network is currently running at these experimental facilities (Pinto, 1996). Its aim is to make a significant contribution to the updating and application of Eurocode 8, which will increase the competitiveness of the European Design and Construction industry in earthquake prone areas. Three full/large-scale models of buildings and assemblages will be tested at ELSA, in order to investigate: a) suitable retrofitting solutions and techniques for existing buildings constructed without appropriate seismic resisting characteristics, b) innovative design methods leading to safe and more economical structures and c) the design and detailing of reinforced concrete shear-walls of non-rectangular cross-section (U-shaped and L-shaped walls) (Pinto, 1998).

The ELSA laboratory is also open to the European industry to develop and qualify new construction/strengthening methods and technologies. Furthermore, National and Regional Authorities can take advantage of this unique facility as happened in the monuments field, with involvement by the Sicily Region and the Directorate-General for Monuments in Portugal.

Competitive pre-normative research in support of Eurocode 8

The ELSA laboratory and four European institutions recently concluded a competitive pre-normative research project launched by DG-III on the seismic assessment of structures, focusing on composite (steel-concrete) structures and reinforced concrete frame buildings with ceramic-brick infill panels. In fact, there was a lack of data and sound scientific basis for the design of infilled frames considering explicitly the effects of the infill-walls and for the design of composite structures as conceived in Europe.

Concerning the structures with infill panels, it should be noted that the design of such structures according to national codes does not consider the effects of the infill panels in the resistance and performance of framed structures. On the other hand, Eurocode 8 is a pioneer in the field, including specific clauses applicable to such structures.

The problem concerning composite structures was even more difficult. Several knowledge gaps requiring further research in the field of composite structures under cyclic loading were identified. In particular, there was need for further research on the topic of proportioning and detailing of composite members and subassemblies for satisfactory energy dissipation. It is expected that such a rich data base on composite structures and the theoretical work developed so far can make a significant contribution to drafting the Eurocode 8 chapter on composite structures, which is due to be voted on and included in the normative part of the code.

The research activity for the near future

A new institutional activity, funded by the Fifth Framework Programme, on seismic protection of civil and cultural heritage structures, will focus on innovative techniques for strengthening existing structures (buildings and bridges) and on the evaluation of seismic risks of monumental structures and development of suitable protection systems.

Two aspects of this should be underlined:

- One is the experience from the recent major earthquakes (e.g. Northridge 1995 and Kobe

1996), which indicates that more emphasis should be placed on the seismic strengthening of existing structures. In fact, the major causes of deaths and serious damage were in fact the lack of appropriate resistance of the buildings constructed according to old design codes.

- The other one is the vulnerability of existing monumental structures, clear after the Umbria/Marche earthquake crises of 1997 in Italy. Serious damage was inflicted on important monuments such as the San Francesco of Assisi churches and beautiful old towns were completely destroyed by the quake.

When trying to find an economic and technical solution, the successful mitigation of risks should be tackled through a research programme of adequate proportions. This should be defined in terms of the development and assessment of appropriate solutions and techniques for seismic protection including protective systems such as base isolation, dissipation and active control. There is also the question of how to put the scientific and technical findings into practice effectively.. The answer is quite simple; first of all it is necessary to codify the results from the research, translating them into specific design provisions. Then, major efforts should be made by local, regional, national and international authorities as well as by private institutions or individuals to set-up and develop intervention programmes.

Conclusion

The research activities at ISIS on the earthquake protection of civil and cultural heritage structures presented above cover a broad range of applications and objectives. However, the overall scope of all these research programs is to contribute to development and up-grading of design codes, specifically Eurocode 8 -the European design code for structures in earthquake prone areas. The advantages of a uniform code in terms of safety and economic impact have been already highlighted. The difficulties in reaching agreement in specific subjects related to very different design and construction traditions or to very-low versus high seismicity approaches have been also mentioned. The question is now how to overcome such difficulties in order to make headway.

From experience, we are convinced that the key to success lies in cooperative research projects involving teams from different European countries, including also international collaboration. The recent co-operation agreements signed between the Commission and third countries (e.g. Japan, United States and Australia) in the research and technological field will certainly contribute to a more advanced and common approach in these fields. Also, the co-operation agreements between the JRC and Japan and American Institutes in the field of earthquake engineering will play a decisive role in the earthquake protection issues, contributing to the effective development of such international cooperation.

Furthermore, a more direct connection between research and CEN technical committees is needed. In this respect, the newly signed agreement between the JRC and CEN/STAR will certainly have a positive impact (JRC, 1998). However, there are also some aspects we should try to face such as the financial support for the co-operative projects mentioned above involving national institutions and experts, in addition to the JRC. Financing of such activities in a broad sense, considered only under one programme title (European Added Value), may lead to uncoordinated actions. Specific research funds for pre-normative and co-normative research in support of European standards made available on a competitive basis, could alleviate this problem.

Keywords

EUROCODES, Large-scale Testing, Pre-normative research, Seismic tests, Pseudo-dynamic tests

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Industry Consortia and the Changing Roles of Standards Bodies and Regulators

Adam Watson Brown, *DG-XIII*

Issue: *Ad hoc* groups like the Digital Video Broadcasting Group and the Digital Versatile Disk consortium represent a collective approach to pre-standardizing new broadcasting systems and associated consumer electronics products. By pre-digesting all commercial differences prior to the standardization process, they speed it up substantially. Their approach is driven by considering and reconciling different business models rather than technology push.

Relevance: The success of this market-led model opens the way to a new approach in broadcasting. Instead of mandating particular transmission standards, the Commission has mandated only that the system(s) be standardized. The new model has also redefined the relationship between research, standardization and regulation in this sector.

Catastrophe encourages collaboration

The massive rewards to be reaped from setting *de facto* standards in the market have traditionally provided an incentive for companies in the consumer electronics market and other converging sectors. The stream of royalties that have enriched JVC – as developer of VHS – and Philips and Sony – developers of the audio CD – continue to flow. However, the downside is the high risk of losing the standards battle. The damage to the loser is profound. First there is the loss of credibility to the brand; consumers question the reliability of the brand when a product is withdrawn like Betamax. Second, the financial effects of withdrawing any product from the market are orders of magnitude more severe compared with closing down a project in the research or development stages given the prevailing ratios in the industries in question: each $1 of research requires $10 of investment in development and $100 to bring the product to market. The heavy capital investments necessary to render any digital consumer product into ICs (integrated circuits) mean that the $100 may be much higher now than in the analogue 1980s when this ratio was first widely promulgated. The primary motive behind group pre-standardization consortia is to resolve issues at the $1-10 stages rather than in the market.

Earlier catastrophes have played a strong role in encouraging collaboration in two recent consortia, the Digital Versatile Disk and the Digital Video Broadcasting Group. DVD includes the consumer video disk application that had totally failed in the 1980s, after years of development, thanks to the videorecorder and its

Setting de facto market standards is highly profitable, but the risks of the lost investment and damage to consumer confidence resulting from someone else's standard winning the race can be enough to put off many players

Past catastrophes have played a strong role in encouraging collaboration in two recent consortia to find standards for Digital Versatile Disk (DVD) and Digital Video Broadcasting (DVB) technology

A major difficulty was the lack of any mechanism able to reconcile the different business models used by consumer electronics manufacturers and broadcasters. Traditional broadcasters would have faced considerable expense without any increase in advertising income

USP (Unique Selling Proposition) of home recording, in addition to packaged video media. Three different video disk formats had reached the market, promoted by RCA, JVC and Philips. The failure of the RCA format dealt a deathblow to the company[1]; Philips was able to retread its Laservision technology into the CD format in alliance with Sony; JVC could console itself with the success of VHS.

Most European DVB members acknowledge that the failure of the digital TV transmission standard (D2-MAC/HD-MAC) strategy for high definition TV (HDTV) had been a major stimulus to finding another approach. DVB itself was born from the ashes of HDTV in 1992. To understand the new DVB approach, it's necessary to summarize the main drawbacks of the HDTV strategy.

A major difficulty was the lack of any mechanism able to reconcile the different business models used by consumer electronics manufacturers and broadcasters. The threat of a Japanese standard put HDTV on the critical path for European consumer electronics manufacturers. Broadcasters, however, perceived it as less of a threat. Moreover HDTV would have been very expensive for them, and would not have increased advertising or licence fee incomes. Pay TV broadcasters championed a more cost-effective business model for broadcasters using digital compression to add additional standard definition channels. Pay TV broadcasters planned to use these additional channels to segment their audiences by interest, through thematic channels.

Apart from a warring value-chain, another major difficulty was the involvement of regulators in underwriting the entire strategy, rather than the market itself. The European Commission's involvement began with an innocent enough request from the EBU to mandate the MAC family of standards prior to the start of the satellite TV market in order to avoid the "uncommon market" caused by the PAL and SECAM TV standards. The addition of HDTV blurred the line between regulation in support of standardization and industrial-policy style promotion of particular market outcomes. Commission involvement politicized the whole HDTV activity. Member States also played a role by adopting different versions of the MAC standard. This caused industry to hesitate over marketing MAC products, thereby initiating a series of delays that were a major factor in the failure of the whole enterprise, with market launch being delayed from 1984 to 1992[2].

The DVB model is market-driven

The DVB model solves these difficulties, and some others, by bringing together broadcasters and manufacturers. System specification begins with the drafting of commercial user requirements. The business models of different parts of the value chain have to be reconciled during these discussions. They need to solve the "HDTV and/or multiple channel and at what cost to whom" issue. Comparably, in the DVD consortium, some of the most difficult discussions took place on copyright protection. Hollywood studios want to protect their valuable property, while manufacturers had traditionally resisted any attempts to impose anti-copy technologies and limit functionality.

Once DVB has a set of commercial user requirements, it then configures appropriate technologies to match these requirements. DVB has taken a smorgasbord approach to choosing technologies: from EU research programmes, Eureka, national research or members' in-house research. At the core of all DVB systems lies the MPEG2 compression system defined by companies working at global level through ISO. There is no dependence on a single project or

programme to provide a turnkey solution – as with the high profile Eureka 95 HDTV research project. It is the opposite approach from the old style European one: develop the technology and then think of an application for it (D2-MAC had been widely criticized as a technology solution looking for a problem); it offered an improved technical approach at extra cost without any major benefits over PAL to most broadcasters. In contrast in the case of DVB standardization is almost incidental; DVB transmits the finished specification to ETSI. The standardization process is no longer burdened with extraneous issues, especially trying to reconcile different companies' strategies on the "engineers around a table" model.

In the DVB or group model, research alone cannot drive standardization because researchers do not have full knowledge of the business model. The commercial requirements of the business model drive the DVB process. One observes an iterative process between research and commercial requirements. This is the essential point. Researchers can at best offer an initial configuration or application of a particular technology. For instance, four years ago ADSL (Asymmetric Digital Subscriber Line) network transmission technology was promoted as the solution for video on demand. However, extensive market research by British Telecom and others indicated that it would be too expensive and gain only a limited acceptance. Now ADSL is back, this time reversioned for fast Internet access.

The changing role of the regulator

The regulators also moved out of the standards-setting business and let the market players get on with the process. This is another important feature of the DVB model. In 1992, the European Commission decided to separate regulation from promotion. This led to the TV standards directive 95/47 which sets a light regulatory standard for digital TV and a four year action plan to overcome the market failure blocking the introduction of wide-screen television[3]. A key feature of the directive is that it does not mandate any standards for digital TV; it merely states that any DTV transmission system used should be standardized.

Removing the regulator from the activity of developing or mandating standards means that the market actors have to deal with each other, rather than trying to manipulate the regulator. This improves the standardization. Over five years, the DVB has created a series of specifications which cover every type of television service over any delivery mechanism. The "data container" approach means that the transmission systems are fully convergent – they can deliver any type of content including Internet and e-commerce services. DVB transmission systems are being used throughout the world.

By contrast the US process – led by the FCC – has over six years produced a single terrestrial DTV system. This is an unsatisfactory compromise between broadcasters and consumer electronics companies vision of HDTV on the one hand and the computer industry's standard definition requirements on the other. Manufacturers and broadcasters are puzzling over which of the 18 image formats in the ATSC TV transmission system they should implement in TV sets and studio equipment. There are a number of lessons to be drawn from the US example. Placing a regulator at the centre of the process has politicized the process of defining a system and may have produced sub-optimal results both in terms of the ATSC system itself[4] plus an undesirable emphasis on a single type of DTV service in the supporting policy[5]. The mingling of regulation and a promotional objective – HDTV – recalls the MAC saga in Europe.

The different interests in the value chain were brought together as a consortium to define commercial user requirements, after which appropriate technologies could be configured to meet them

An important feature of the DVB model is that the regulators left the business of setting the standards to the market players. The outcome has been a fully convergent set of transmission systems able to deliver any type of content

The regulator's impartiality does not mean inactivity. There is always the tacit threat that if the market actors don't come up with a standard, the regulator may impose one none of them like

One specific problem in the broadcasting field was reconciling the requirement for open access with the pay TV operators' reluctance to subsidize decoders that could be used to access their competitors' channels

The solution that emerged was to mandate one small item of technology for inclusion in all decoders. The scrambling algorithm is not formally open for security reasons, but is held by a neutral third party (ETSI)

In Europe, the regulator's impartiality towards the pre-standardization process and its refusal to mandate standards does not imply inactivity. A key element in the game theory of the DVB is the threat that if the market actors cannot agree among themselves to resolve a particular issue, the Commission may impose a solution that everyone will disagree with. Moreover, where there are specific difficulties which the market actors cannot solve alone, the Commission has played an important role.

Conditional access (CA) was the first test of the new regulatory approach. Many broadcasters feared that pay TV operators' control over conditional access systems embedded in subsidized digital TV decoders would lock them out of the market. Directive 95/47 requires these proprietary CA systems to be made available on "fair, reasonable and non-discriminatory" terms to third parties, a concept well-understood in the open network provision (ONP) environment[6]. Moreover the competition rules continue to apply in this market, as in any other, as a final line of defence[7].

At the technical level, the problem was how to achieve interoperability between different pay TV platforms. The old fashioned approach would have been to mandate a single, standardized, conditional access system in order to achieve open access all the time for third party broadcasters. This was however entirely unacceptable to pay TV operators for both business and security reasons[8].

The Commission was faced with a difficult choice as a regulator. Pay TV operators were expected to be the sole market drivers in the early stages of the market because their business model enables them to subsidize the cost of decoders. Open access by other broadcasters to subsidized decoders would have created a "free rider" problem and destroyed any incentive to subsidize decoders. On the other hand, there are public interest requirements which militate in favour of openness and interoperability, notably the consumer interest in having a single decoder to receive all DTV services and the traditional democratic and cultural roles of broadcasting. There was a need to balance incentives to the economic "first mover" with the rights of "second movers" who feared that they would be excluded by digital "gatekeepers".

The Commission was offered a choice of two interoperability techniques by the DVB, simulcrypt and the common interface. Simulcrypt is a set of technical procedures that achieves interoperability between decoder populations containing different, embedded CA systems, essentially by transmitting additional CA keys for each decoder population, following commercial agreements between the market parties. The common interface places all CA elements on to a detachable PCMCIA module (Personal Computer Memory Card International Association) so the decoders are not specific to any CA system. To change between different platforms, the viewer swaps modules. Pay TV operators have security and business model objections to the common interface, as described above. The political discussions were long and difficult.

The solution that emerged was to mandate one small item of technology for inclusion in all decoders. The common scrambling algorithm is essential for achieving interoperability between CA systems and underpins both simulcrypt and the common interface. It is not formally an open standard for security reasons, but is held and licensed by ETSI (European Telecommunications Standards Institute) as a neutral party[9]. The relevant directive also accepts either approach to interoperability.

Conclusions

In the audiovisual domain, the value chain is complicated and contains a number of interdependent sub-sectors with different business models, notably consumer electronics manufacturers on the hardware side, and broadcasters and media companies on the "soft" side. Sometimes there are even different business models within one part of the value chain, for instance pay TV and free-to-air broadcasting. The creation of new digital platforms like DTV or DVD poses far reaching challenges to all business models.

Unless the different market parties are able to reconcile their different requirements in a neutral framework, failure of a new technical platform is almost guaranteed. Collaborative groups like the DVB provide a means of reconciling different business models and achieving consensus at sector and firm level. Once agreed, the resulting specifications can be rapidly standardized by standardization bodies without the political/commercial disputes that have slowed down standardization procedures historically. The principle role of the regulator is to ensure that externalities are taken into account in a way that is proportional. Clearly the need to promote competition and ensure market entry is the most important, given that health and environmental considerations are already covered by other horizontal measures[10].

A research or regulator-driven approach to standardization no longer operates effectively in industries with complicated value chains with many different types of market player. If the regulator places itself at the centre of such a process, market actors will concentrate on trying to manipulate the regulator. An obvious gambit is to try and get the regulator to mandate standards in order to reduce downside risk or to disadvantage other players. The regulator should therefore focus narrowly on specific problems where the market players cannot provide a solution.

The CA example shows how it is even possible to accommodate proprietary technologies with appropriate regulatory safeguards, outside the normal standardization framework. The TV standards directive stipulates that CA be made available on fair, reasonable and non-discriminatory terms. This is important because the speed of technological development and the move towards software-based functionality mean that proprietary solutions always come first, with openness and interoperability as a secondary consideration.

The flexibility of software solutions now means that industries are less prisoners of their installed base than in the hardware-dominated analogue era. For instance, the first generations of APIs (Application Program Interface) for TV decoders are frequently proprietary. However, the conceptualization of a second generation DTV receiver architecture[11] within the DVB provides an opportunity to define a more open approach to APIs, while retaining compatibility with existing ones. The DVB process provides an opportunity for the collective wisdom of the group to address the API issue and arrive at a superior solution that recognizes all business models.[12] In this area, regulators therefore need to adopt a more proportional approach to standardization, mandating only what is absolutely necessary, to support interoperability on commercial terms, for instance.

Keywords
television standards, DVB, ATSC, television transmission, regulation, digital transmission

Notes

1- Margaret B.W. Graham, RCA and the Videodisc: the business of research, Cambridge University Press, 1986.

2- In 1984 the European Broadcasting Union wrote to the European Commission requesting that the MAC family be the mandated European standards for satellite television. In 1992, European manufacturers abandoned HD-MAC, the analogue HDTV transmission system.

3- The four year Action Plan 1993-1997 offered a financial contribution to broadcasters and programme producers as a contribution towards the additional cost of introducing 16:9. Note that the Action Plan also left the choice of transmission system for wide-screen TV to the market players. Council decision 93/424/EEC of 22 July 1993, OJ L196/48, 5.8.93.

4- For instance, one broadcaster's suggestion at NAB 1998 that ATSC should substitute COFDM modulation for VSB in order to achieve more robust reception through fixed antennas and mobile reception, points also extensively discussed in at least one ATSC internet discussion group such as **opendtv-digest@pcube.com**. Note also that the scope of the ATSC work mapped on to the mandate of the FCC – terrestrial– rather than the entire market. Satellite and cable are included in the DVB architecture.

5- The whole strategy is underpinned by a massive subsidy: an additional 6MHz channel for every broadcaster in the US. This is far more than is necessary to migrate terrestrial broadcasting to DTV at standard definition, because the FCC wanted broadcasters to introduce HDTV services. Recall that HDTV is the most expensive form of digital television – compared with multiple channel standard definition services – even if it achieves maximum differentiation from analogue standard definition services by offering much greater impact and realism: 16:9 wide-screen aspect ratio; big screen; multi-track audio. However, the costs of HDTV mean that it is unlikely to achieve universal penetration compared with other forms of DTV. The issue is whether a regulator backs a particular service preference using scarce terrestrial spectrum.

6- In addition all decoders must pass free-to-air services and integrated DTV sets must allow the option of fitting a standardized connector.

7- There have been some significant merger cases in the DTV area, notably MSG, Commission Decision 94/922/EC of 9 November 1994; Deutsche Telekom/Beta Research M.1027, 27/05/98; Bertelsmann/Kirch/Premiere M993 27/05/98.

8- Pay TV operators argue that a single CA system is vulnerable to attack from hackers. If each operator has its own CA system, each can take technical measures without having to depend on other operators.

9- **http://www.etsi.com**

10- For instance, Directive 89/336/EEC in respect of electromagnetic compatibility. See also Directive 99/5/EC on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity.

11- The Multimedia Home Platform (MHP). See **http://www.dvb.org**

12- There are some intriguing parallels with the open source software movement in the computing world. See for instance "Software that has been developed by thousands of volunteers and is given away is often better than the stuff for sale", The Economist 20 February 1999.

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The **IPTS** is one of the eight institutes of the Joint Research Centre of the EU Commission. Its remit is the observation and follow-up of technological change in its broadest sense, in order to understand better its links with economic and social change. The Institute carries out and co-ordinates research to improve our understanding of the impact of new technologies, and their relationship to their socio-economic context.

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