

## Office of Management and Budget

### **BSI response to Request for Comments: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities**

BSI would like to offer some British and European perspectives on the relationship between voluntary standards and regulations.

#### Introduction

The voluntary, market-led consensus-based standards making system has generally worked well for the world; bringing significant benefits in terms of increased competition, the diffusion of innovation, economic growth and the free trading of goods and services. In Europe, as in the US, the interface between standards and regulations is under constant review to achieve an improved balance between the different demands of political policy interests, industry requirements and consumer and environmental protection.

#### Standards and regulation

In the European Union, policy interests are expressed through common European Directives which are agreed by the member states and enacted by them in their national laws. Historically, regulations of this kind tended to be highly detailed in their requirements and highly prescriptive in the means by which compliance could be achieved. However, it was long recognized that regulations of this kind were difficult to draft and agree, required frequent amendment and acted as a drag on innovation. Starting with the Low Voltage Directive in 1973, the EU drew a clear distinction between mandatory Regulations and the voluntary standards that provide a useful, but non-exclusive, means of compliance with them.

The Low Voltage Directive set out essential safety and other requirements that all low voltage equipment had to meet, but referenced voluntary European Standards as a means of ensuring compliance for the many different types of device covered by the regulation. This proved so successful it became formalized as the 'New Approach'.

The distinction between essential requirements and voluntary means of compliance is the fundamental principle underlying the New Approach Directives published by the European Commission (EC).

## New Approach Directives

Once a Directive is agreed, a requirement for supporting standards is identified and a request is made to the European standards bodies for the standardization activity needed to address the policy requirement. This is done by means of a mandate to the relevant body (CEN, CENELEC or ETSI). The standard body then refers the mandate to the appropriate standards committees to confirm that the proposed standard meets a market need and that there is a good prospect of achieving consensus. Once the mandate is accepted, the work proceeds as a contract between the EC and the standards body.

Eventually the standards are published as 'harmonized' European standards (ENs) and are listed in the Official Journal of the EC. Each national member of the European standards body (e.g. BSI) then implements the harmonized standard as its own national standard (e.g. as BS EN) and withdraws any standards that might conflict with it.

In Europe, the New Approach is well established and there is now a general understanding that the standards referenced by Directives are only one way by which compliance may be ensured. Compliance with a 'harmonized standard' gives a presumption of compliance with some or all of the essential requirements of a Directive but anybody is free to choose alternative routes to demonstrating compliance.

At any time, harmonized standards represent the agreed best practice in industry for meeting the policy requirement. The determination of this best practice is achieved through a process that will have involved industry, consumers and government representatives, and all standards are submitted to a period of open public enquiry during which any person may submit a comment.

Compliance with harmonized standards offers effective, efficient and reliable access to the European market but, we repeat, does not preclude access by other, perhaps more innovative, or more appropriate, means.

BSI believes that the New Approach principle has advantages for regulators, for industry and for society in general.

The 'New Approach' helps regulators because:

- it focuses on essential requirements so makes it easier to achieve agreement;
- it reduces the requirement for technical expertise amongst the regulators; and
- it reduces the need for continual regulatory amendment as technology evolves.

It helps industry because:

- it involves them in the process of specifying the means of compliance so that they reflect both technical and business realities; and
- it allows them to achieve compliance in other, potentially more effective, ways.

It helps society because:

- it ensures that consumers and the public can comment on all drafts; and
- the referenced standards provide a benchmark that other means of compliance must match.

### **Access to standards**

Because standards referenced in regulation are not mandatory they are not official documents and their ownership (including copyright) usually rests with private standards organizations. In most cases access to a standard is therefore not free of charge. However, they are easily accessible to those that wish to use them, in different formats, through a variety of channels, on what BSI would argue are reasonable commercial terms.

These charges are necessary for maintaining the standards infrastructure, the cost of which is considerable if the system is to fulfil the requirements of transparency, openness, rigour and full stakeholder engagement.

In addition, BSI and all other European standards organizations make standards available to educational bodies and public libraries on very favourable terms. In these cases they can be accessed for reference purposes by students and the general public free of charge at many different locations.

### **Free standards**

It has often been contended that charging for standards discourages their use, but BSI maintains that voluntary standards will only be used if they add value to the user's organization. Because they contain peer-reviewed knowledge of best practice in their given sectors and offer a quick, cheap means of ensuring regulatory compliance, their value to the user will be vastly greater than their cost.

If standards were to be made free of charge it would require full funding of the process of development, publishing and distribution, either by industry or, more probably, by government and this would compromise the integrity of the system by giving too much influence to one group of stakeholders. In particular, the independence of the standards making bodies would be lost if the system was effectively nationalized and

this would damage the national innovation infrastructure and the capacity of industry to respond to market opportunity in a timely manner.

The experience of the past 60 years is that thought leadership amongst the international standards makers has always rested with those bodies that are unencumbered by the burden of political direction. BSI would never accept that consensus standardization could be directed by government, or that the copyright in the standards BSI develops with industry and other stakeholders could be bought by any government to be converted into regulation, for two reasons:

- Firstly, BSI would become an agent of government and would be unable to defend its independent status
- Secondly, BSI and its standards committees are not elected and are not qualified to act as lawmakers, either in the UK or in Europe.

### **Standards referenced in regulations as public documents**

If standards become mandated in regulations they may be designated as 'official texts' and in some countries this can result in the loss of their copyright protection. However, this does not apply to voluntary standards that are referenced in the regulation.

This issue was addressed in the Netherlands in the recent Knooble case. The Netherlands standards body (NEN) was challenged by a construction engineering company (Knooble) which claimed that standards referenced in legislation were part of the law and should be made freely available. The Dutch High Court found against this in 2010, ruling:

- that NEN standards referenced in building legislation are not binding requirements;
- that standards development committees have no regulatory competence;
- that standards are often only test methods;
- that compliance with standards was not mandatory if an equivalent result could be achieved in other way; and
- that standards are adequately publicized by NEN.

In Germany the issue was addressed even more directly in paragraph 5 of the German Copyright law, which states:

#### **§ 5. Official Works**

- (1) There is no copyright on laws, regulations, official decrees and official announcements nor on decisions and official guidelines on decisions.

- (2) The same applies to other official works which have been published in the official interest for the information of the public, with the restriction that the provisions regarding the ban on modification and the acknowledgement of quotation given in § 62 section 1 to 3 and §63 section 1 and 2 are to be applied accordingly.
- (3) *The copyright on private collections of standards is not affected by section 1 and 2 if they are referred to in laws, regulations, decrees or official announcements without reproduction of their wording. In this case, the originator is obliged to grant each and every publisher the right to copy and distribute on reasonable terms. If a third party is the holder of the exclusive right to copy and distribute, that party is obliged to grant the licence of use in accordance with sentence 2.\**

\* Unofficial English translation for information only

### Standards referenced in regulations: a British example

In the UK there have been some historical anomalies, but citing British Standards as the sole means of regulatory compliance was seldom used and those regulations that did so have now been amended. A requirement for mutual recognition of product standards for international trade has improved the wording in regulations, by making reference to standards non-exclusive, as in the following case:

The Wheeled Child Conveyances (Safety) Regulations 1997 expressly states that:

*'Where there is a requirement in any provision of these Regulations that a wheeled child conveyance, perambulator or pushchair shall conform to a **British Standard** (in whole or in part), such requirement shall be satisfied if the wheeled child conveyance, perambulator or pushchair conforms to **any standard or specification** recognized for use in a member State of the European Economic Community or any other State within the European Economic Area, **provided that conformity to such a standard or specification provides a level of safety at least equivalent** to that which would be provided by conformity to the relevant British Standard (or to the relevant part of such standard), and any reference to such a requirement shall be construed accordingly.'*

In the current wording of the regulation, the British Standard is only one way to achieve compliance and any references to the British Standard in the regulation are to be construed as references to any other equivalent standard.

## Maintenance and currency

There is an inherent conflict between keeping standards up to date with technological and market developments and ensuring a reasonable degree of stability for their user communities, particularly small and medium sized enterprises. This tension is exacerbated in the case of standards 'incorporated by reference' in regulation, as it is usually neither feasible nor desirable to make frequent amendments to legislation.

The European 'New Approach' has offered a partial solution to the problem, but BSI's view is that it can still be unduly cumbersome in operation and that standards and regulations should be explicitly decoupled in such a way that:

- the regulator accepts that the current version of a particular standard will always be the most appropriate for regulatory purposes (e.g. by citing a specific safety standard by 'undated reference'); or
- the regulator puts in place a mechanism to indicate exactly how, to what extent and in what respects, compliance with a particular standard offers a presumption of compliance with the legislative requirement.

The first approach requires either a high degree of trust in the standards body on the part of the regulator, or else a level of influence in the standards making process that many other stakeholders might find unacceptable.

BSI believes that the second approach is preferable and is now quite feasible using websites and similar means of controlled information dissemination. Base legislation published on line could contain links to a website where users could find the appropriate and current regulatory interpretation of a particular reference. This could easily be updated as standardization develops in response to market and technological changes.

BSI believes that this approach is practicable and allows a high degree of flexibility, to the regulator, to the standardizer and to the user community.

## Conclusion

BSI recognizes that standards bodies have a responsibility to facilitate and support the public policy interest. We believe that reference to standards is a necessary and valuable tool for regulators but it must be employed with full understanding and in a way that maintains a balance between the needs and interests of the regulator, of industry and of the consumer. If any one of these three becomes dominant in the national infrastructure, then the system will quickly lose momentum and international standing.

BSI's recommendation is to promote the use of voluntary standards in support of regulation to industry and consumers as an efficient, effective but non-exclusive means to demonstrate compliance with a policy requirement. It will be for US government lawyers to craft the appropriate words and to define the ways in which its agencies should work with standards makers, but the general principles that BSI advocates are already well established in the US and BSI can report that their efficacy has been confirmed by the European experience.

### About BSI

BSI is the UK's National Standards Body, incorporated by Royal Charter and responsible independently for preparing British Standards and related publications. BSI has 111 years of experience in serving the interest of a wide range of stakeholders including government, business and society.

BSI presents the UK view on standards in Europe (to CEN and CENELEC) and internationally (to ISO and IEC). BSI has a globally recognized reputation for independence, integrity and innovation ensuring standards are useful, relevant and authoritative.

The content of this note constitutes BSI's understanding of the relationship between standardization and regulation and is not intended to be, nor should it be relied upon as, a definitive statement of the law on this matter

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